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Award Number: W81XWH-06-1-0651

TITLE: “Medical Device Plug-and-Play (MD PnP) Interoperability Standardization Program Development”

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REPORT DATE: August 2009

TYPE OF REPORT: Final, Phase II

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: (Check one)

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REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*
8-31-2009

2. REPORT TYPE
Final, Phase II

3. DATES COVERED *(From - To)*
1 JAN 2008 - 31 Jul 2009

4. TITLE AND SUBTITLE
"Medical Device Plug-and-Play (MD PnP) Interoperability Standardization Program Development"

5a. CONTRACT NUMBER
W81XWH-06-1-0651

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Massachusetts General Hospital
Boston, MA 02114

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research
and Materiel Command
Fort Detrick, Maryland 21702

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This BAA provided core program support to develop key capabilities of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to lead the evaluation and adoption of open standards and technology for networking medical devices to support clinical solutions for improved patient safety and healthcare efficiency. Towards these goals, a medical device interoperability lab was created at CIMIT in Cambridge, MA, as a vendor-neutral, shared collaborative resource; clinical use cases demonstrating the capability of medical device interoperability to improve patient safety were developed and exhibited at major national conferences; Part I of a multi-part international standard (ICE) describing the functional architecture and risk mitigation strategies for networked patient-centric interoperable medical devices was written and is being published by ASTM International; a conference on "Improving Patient Safety through Medical Device Interoperability & High Confidence Software" was held, with a subsequent workshop; a working group of MD PnP collaborators was convened.

15. SUBJECT TERMS
Medical device, plug-and-play, interoperability, patient safety, device control, health care, standards

16. SECURITY CLASSIFICATION OF: a. REPORT	b. ABSTRACT	c. THIS PAGE	17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
U	U	U	UU	62	USAMRMC

19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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Principal Investigator: Julian M. Goldman, MD
Period of Performance: January 1 2008 – July 31 2009

Introduction

A May 2004 symposium jointly sponsored by TATRC (U.S. Army Telemedicine & Advanced Technology Research Center) and CIMIT (Center for the Integration of Medicine & Innovative Technology) kicked off what became the Medical Device "Plug-and-Play" (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical, technical, and regulatory requirements, and began to define an agenda for standards development. By the time of the second TATRC-sponsored symposium in June 2005, the stakeholders had acknowledged that the need for interoperability encompasses the full continuum of high-acuity healthcare environments, so the program developed a strategy to accelerate the development of interoperability technologies and standards. The strategy addressed the need for a "sandbox" laboratory environment to facilitate the testing of devices and technology with proposed standards; the development of a "plug-and-play" system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors' legal concerns; and assuring the clinical relevance of proposed interoperability solutions.

TATRC awarded this BAA grant to provide foundational support to enable the MD PnP interoperability program to develop in accordance with this strategy. During Phase I (14 July 2006 – 13 January 2008), we developed and extended key capabilities of the program, and TATRC's commitment enabled us to attract additional program funding from Partners HealthCare Information Systems. The Phase I support of core personnel allowed us to identify and access numerous other resources and to build collaborations to achieve BAA objectives. Specifically, a medical device interoperability lab was created in May 2006 at CIMIT in Cambridge, MA as a multi-institutional, interdisciplinary shared resource; clinical use cases demonstrating the capability of medical device interoperability to improve patient safety were developed and exhibited at three national meetings; a draft international standard describing the functional architecture and risk mitigation strategies for networked patient-centric interoperable medical devices was written; and an international conference on "Improving Patient Safety through Medical Device Interoperability and High Confidence Software" was held. [1]

The Phase II (14 January 2008 – 31 July 2009) core program support enabled the MD PnP interoperability program to achieve the writing, submission, and approval of a key medical device integration standard – the Integrated Clinical Environment (ICE) standard, Part I, which is being published by ASTM International in Q3 2009. In addition, we led a successful collaborative effort of three major healthcare providers to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. Seven medical societies – most recently the American Medical Association – have now endorsed medical device interoperability for improving patient safety. We worked with three companies who received DoD SBIR Phase I awards to develop an ICE Supervisor for trauma assistance. TATRC BAA support was instrumental in providing "program glue" to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

Body of Report

The MD PnP Program has become a recognized leader in the evaluation and adoption of open standards and technology for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency. Interoperability will enable the creation of complete electronic health records and will introduce error resistance into medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support interoperability for effective clinical deployment. This will require critical evaluation (or “gap analysis”) of potentially suitable candidate standards, and is likely to require the modification of existing standards and development of new standards for implementation in the MD PnP standardization framework. By leveraging available standards, we expect to accelerate the MD PnP standards framework development, so that useful candidate standards can be vetted and demonstrated within three to five years. This will include defining an appropriate regulatory pathway for networked medical device systems in partnership with the U.S. FDA, and developing the MD PnP Lab as a “sandbox” populated with medical devices and test equipment to serve as a vendor-neutral environment to perform interoperability testing and conformance testing to evaluate proposed standards.

Over the course of this grant, we identified five interdependent and synergistic themes for the MD PnP work:

Standards Development
To develop and achieve adoption of a standardization framework for medical device interoperability that has the support and buy-in of all stakeholders, the MD PnP program must ensure an open development environment. An independent, vendor-neutral program can act as the catalyst to bring the developers of proprietary software and systems to the table together with their clinical customers and government regulators to achieve this goal. The MD PnP program has been successful in contributing leadership, clinical requirements, and technical expertise to standards development organizations that are developing interoperability-enabling standards (e.g. IEEE and ASTM International). Establishing a framework for such standards begins with standards for an “Integrated Clinical Environment” (ICE) to define the conditions under which interoperability can be successful. We have led the drafting and submission of the ICE standard, Part I, under the auspices of ASTM International, and we plan to continue this work by convening the writing groups to produce subsequent parts as needed (e.g. network control, device models and ontology, etc.).

Open Clinical Platform Development
During the course of this grant, we have used the MD PnP Lab to develop demonstration implementations of clinical use cases in which integrating the clinical environment will improve patient safety. These use case implementations have been shown at major clinical and health IT conferences. With CIMIT funding we have been working on the first instantiation of an open platform for clinical delivery of MD PnP functionality: the Medical Device Mobile Plug-and-Play Platform™ (the MD MP3™). Our initial prototype implementation has focused on an error-resistant patient-controlled analgesia (PCA) medication delivery system with safety interlocks, based on PCA / monitor interoperability. This prototype provides the foundations for an open research platform that could support evaluations by the FDA of MD PnP systems and serve as a generic model that could be shared with other organizations developing, for example, open device software adapters and ICE Part I reference architecture.

Clinical and Engineering Requirements for MD PnP
The need to base our work on clinical use cases and requirements was identified by all stakeholder groups as critical to the production of a clinically valid standardization framework. Initiated during the first year of the program, our activity in eliciting and analyzing high-level clinical user requirements for MD PnP has been ongoing. The raw input from focus group sessions was organized into defined clinical scenarios or “use cases”, which were presented back to earlier participants for refinement and then used to elicit feedback from new clinical sources. Several clinical scenarios were incorporated into the ICE Part I standard, and a team of MD PnP collaborators has been performing detailed workflow analysis of these use cases and analyzing the ability of existing standards (like IEEE 11073) to meet these requirements.

Collaborators working on ICE-related development projects have an ongoing need for additional high level clinical scenarios to be developed into clinical requirements.

Program Development and Management

Convening diverse stakeholders and maintaining their engagement has been a key focus of the MD PnP program and a good fit with our home in CIMIT. To date we have convened five plenary meetings to bring stakeholders together for information exchange and discussion of issues related to achieving medical device interoperability. These meetings have been sponsored jointly by TATRC and CIMIT and by TATRC and NSF through conference grants, by the FDA, and by NSF's Cyber Physical Systems group. This BAA has enabled us to hold smaller working group meetings to develop program strategy, to work on methodology, to develop MD PnP demonstrations, and to draft the ICE standard. In addition to meetings, our web site (http://www.mdpnp.org/) has provided information about the program, including streaming video of the talks from the May 2004, June 2005, and June 2007 meetings. During the period of this grant, we have made substantial gains in getting medical devices to be part of the national dialogue on interoperability, and the PI remains actively involved in this effort. [2]

Regulatory Pathway

An early premise of the MD PnP program has been that the goal of medical device interoperability standardization can only be achieved by working closely with the FDA, and this has been the approach to date. The mutual objective of the FDA and the MD PnP program leaders is to identify a regulatory pathway that will support the MD PnP concept, i.e. which will support safe integration of devices and not require re-validation or re-clearance of the entire system as each new independently validated device is added to the MD PnP network. Over the past four years we have studied and elaborated the issues and concerns surfaced by medical device interoperability stakeholders, and have increased the community's understanding of them. We are continuing to pursue opportunities to work with the FDA in standards development activities, in discussions of the solution pathway offered by ICE, and on projects with our collaborators involving safety studies.

Research Accomplishments Related to Statement of Work

For Phase II the following objectives were identified:

Standards Development

- Address comments on the draft ICE standard, Part I, following submission as a New Work Item Proposal (NWIP) to ISO/IEC; convene and manage the ICE Part I standard development committee to shepherd its progress through the review and balloting process
- Convene the writing group for ICE Part II (device and system models) and manage its work to produce a draft for submission as a NWIP; submit ICE Part II as a NWIP to an SDO (Standards Development Organization)

Open Clinical Platform Development

- Develop prototype hardware and software for the MD PnP system in the MD PnP Lab, e.g. open device software adapters and ICE Part I reference architecture
- In parallel with the CIMIT-funded development of a prototype mobile "plug-and-play" platform (MD MP3™) for improving Patient Controlled Analgesia (PCA) safety, assure future extendibility of the prototype concept by identifying engineering requirements related to a broader implementation of this platform; identify requirements for MD MP3™ to support iterative clinical applications; develop architecture for MD MP3™ to conform to the ICE standard

Clinical and Engineering Requirements for MD PnP

- Expand and refine existing "raw" clinical scenarios as a use case repository for use by others
- Apply our use case / clinical requirements analysis methodology to the PCA use case
- Elicit clinical scenarios from DoD clinicians and from Boston-area nurses

Program Development and Management

- Build collaborations with additional interoperability-focused organizations
- Develop a list of planned MD PnP Lab capabilities for fee-for-service use; submit an NIH/NIBIB Center or Program Grant focused on utilizing the MD PnP program and lab as a national resource for medical device interoperability
- Create multi-year phased program and project plans

Although we had no specific Phase II objectives related to the **Regulatory Pathway** theme, there were some significant accomplishments in this area, which are reported below.

Standards Development

Objective 1: *Address comments on the draft ICE standard, Part I, following submission as a New Work Item Proposal (NWIP) to ISO/IEC; convene and manage the ICE Part I standard development committee to shepherd its progress through the review and balloting process.*

A multi-institutional writing group convened by ASTM International Committee F29 under Dr. Goldman's leadership – including engineers and standards experts from Partners HealthCare System, the FDA, Draper Laboratory, Draeger Medical, MITRE Corporation, Philips Medical, DocBox Inc., and University of Pennsylvania – produced the preliminary draft of Part I of the multi-part ICE standard ("Integrated Clinical Environment") that embodies the elements of the overall technology ecosystem to safely implement networked medical device systems. This draft was submitted by ASTM F29 as a New Work Item Proposal (NWIP) to the IEC/ISO international standards development organizations in late 2007. It received a tie vote in ISO, which was insufficient for adoption as a New Work Item.

During the ISO/IEC review process, the 161 comments that were submitted revealed strong support from clinical institutions and criticism from medical device companies with proprietary interests. The negative comments were systematically reviewed and addressed by ASTM F29.21, which included the original writing group, over the course of many meetings in 2008, resulting in a greatly improved draft standard: "Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)." Part I was re-scoped and re-named "General requirements and conceptual model," and it specifies the outline of subsequent parts (to be written).

As part of the effort to address negative comments on the ISO NWIP, the PI worked with the FDA to convene a meeting in March 2008 at the FDA, to which representatives of organizations that had submitted these comments were invited. The discussions at this meeting were instrumental in ironing out misconceptions and enhancing mutual understanding, which improved both the ICE standard and the relationships with different standards groups working in related areas.

ICE Part I went out to ballot in December 2008 and passed with no negative votes. The comments submitted were addressed by the ASTM F29.21 subcommittee at a meeting in February 2009, and ICE Part I then passed ASTM-wide on March 1, 2009. The standard has been issued the number F2761-2009 and is being published by ASTM in Q3 2009. [3]

Objective 2: *Convene the writing group for ICE Part II (device and system models) and manage its work to produce a draft for submission as a NWIP; submit ICE Part II as a NWIP to an SDO (Standards Development Organization).*

Because the effort to systematically address the ICE Part I comments required substantial rewriting of the draft standard within officially convened standards meetings, this took most of 2008 and the launch of work on subsequent parts had to be postponed. The ICE conceptual model that evolved made it clear that development of Parts II (network controller) and III (device and system models) would need to proceed in parallel, due to the interdependencies of the proposed functionality. Initial discussion of both Parts II and III began in February 2009, and continued at the ASTM F29 meeting in May. Initial drafting of these parts is currently underway in preparation for the ICE meeting to be held at CIMIT in September 2009.

We expect the continuing ICE discussions to be informed by collaborative work being done by Moberg Research Inc. and LiveData Inc. through a Phase II DoD STTR and a Phase II DoD SBIR, respectively, and by four SBIR Phase I contracts awarded by TATRC in 2009 to develop the ICE Supervisor function for trauma assistance. These projects are producing technology that will also inform the future development and architecture of an open ICE development platform.

In addition, collaborative work that is currently underway with two university computer science and engineering groups is expected to inform both the open ICE standard and the ICE development platform. For example, a graduate student working with our collaborators at the University of Illinois / Urbana-Champaign spent the summer of 2008 as an intern at the FDA (Center for Devices & Radiological Health / Office of Science & Engineering Laboratories), working with senior technical staff involved in the MD PnP program. He was focused on safety modeling and analysis for interoperable medical device systems, and he produced a scientific poster showing the relationships of the many aspects of medical device interoperability, including case studies, models and transformations, and safety verification. This poster was exhibited at the 2008 CIMIT Innovation Congress.

Open Clinical Platform Development

Objective 3: *Develop prototype hardware and software for the MD PnP system in the MD PnP Lab, e.g. open device software adapters and ICE Part I reference architecture.*

Although we have been successful in gaining collaborators who want to work with us to advance medical device interoperability, these geographically distributed organizations work primarily on their own campuses or company premises, where they have their own tools and development environments. While they sometimes convene at the MD PnP Lab to integrate their efforts, as has happened in developing MD PnP demonstration implementations, we have not yet had the resources to enable hiring dedicated engineering personnel for the program. Such engineers are necessary to assure progress on our multiple internal projects, as well as external project coordination and progress with our collaborators (see **Objective 9**).

Because our goal is ICE conformance for interoperability solutions, achievement of this objective has been necessarily delayed due to the challenges in completing the ICE standard. However, as a result of our July ICE-PIC meeting (see **Objective 8**), several collaborators have committed to make device adapters they have developed available to others through the MD PnP Lab as an interoperability resource.

Objective 4: *In parallel with the CIMIT-funded development of a prototype mobile “plug-and-play” platform (MD MP3™) for improving PCA safety, assure future extendibility of the prototype concept by identifying engineering requirements related to a broader implementation of this platform; identify requirements for MD MP3™ to support iterative clinical applications; develop architecture for MD MP3™ to conform to the ICE standard.*

Work has been underway throughout Phase II on a platform for clinical delivery of evolving MD PnP functionality: the Medical Device Mobile Plug-and-Play Platform™ (the MD MP3™). This hardware and software platform is intended to support iterative development of MD PnP standards (e.g. ICE) and related technologies for external collaboration. The initial prototype implementation has focused on an error-resistant patient-controlled analgesia (PCA) medication delivery system with safety interlocks and a preliminary data logging (“black box recorder”) function.

Our multi-institutional, international development team is comprised of engineers from three universities in three countries: the University of Pennsylvania, the University of Waterloo (Canada), and the University of Applied Science at Wiener-Neustadt (Austria). They further developed the basic PCA safety demo that was exhibited at the American Society of Anesthesiologists 2007 Annual Meeting, by adding a “medical network” capability and utilizing a set of “device boards” to provide an initial model of what is needed for an ICE platform. We showed this updated implementation as an educational exhibit at the February 2008 annual meeting of HIMSS (Healthcare Information & Management Systems Society).

In our scientific exhibit at HIMSS08, the PCA demo showed how continuous monitoring of the patient’s SpO_2 and respiratory rate could detect the onset of respiratory depression, and how integration of the PCA pump and monitors can automatically stop the infusion, lock out further doses, and activate the nurse call system. The exhibit demonstrated that the plug-and-play capability to easily swap different monitors to assess respiratory function could increase the reliability of problem detection (increase sensitivity) while reducing false alarms. The demo attracted considerable interest from medical device companies and other visitors.

Figure 1. MD PnP Program’s Educational Exhibit & Demonstration on PCA Safety at HIMSS08 (Healthcare Information & Management Systems Society) Annual Meeting, February 2008

The HIMSS08 implementation provided a foundation for development of the mobile “plug-and-play” platform (MD MP3™). The team investigated and identified open architectures that are appropriate for the smaller real-time network interface boards necessary for a mobile cart application. However, prototype development of the MD MP3™ cart was delayed by the unavailability of the small specialized network boards, which were ordered in June 2008 but not delivered until November. In the meantime, the team built on the HIMSS08 implementation and further developed the PCA demo to better show the pairing of devices with the device boards (approximately 6 x 10 inches) representing PnP interfaces. In addition, a prototype implementation of the flight-data-recorder data logging functionality was developed and added to the demo, which was shown at the CIMIT Innovation Congress in October 2008. Among visitors to the exhibit were several officers from TATRC, including Major Gen. George Weightman, as well as Dr. James Peake from the Veterans Administration.

The data logger is a critical component of ICE that addresses liability concerns. Although limited in function for this initial prototype, its implementation is elucidating some of the issues that will need to be addressed in Parts II and III of the ICE standard.

Figure 2. MD PnP Program's Educational Exhibit & Demonstration on PCA Safety at CIMIT Innovation Congress, October 2008

Subsequent to the CIMIT Congress, the MD MP3™ project team further refined the PCA safety implementation to incorporate the new smaller specialized networking boards. The team successfully integrated these smaller (approximately 2 x 3 inches) boards into the prototype MD MP3™ platform as device adaptors. [4] This demonstration for improving PCA safety was shown at the HIMSS09 conference in Chicago in early April 2009 and at the ATA09 conference in Las Vegas in late April, where we were invited to be part of the TATRC booth. Our University of Pennsylvania engineering team made further improvements to the demo for its presentation at TATRC's Advanced Medical Technology Exposition at their OASIS facility in June 2009.

The completion of the cart-based implementation is still pending, but the viability of a mobile MD PnP platform has been successfully demonstrated. The implementation of ICE functionality using the much smaller networking boards makes it possible to visualize the ICE components as either packaged in a "box" near the patient or distributed among locations such as the patient bedside and the nursing station.

Clinical and Engineering Requirements for MD PnP

Objective 5: *Expand and refine existing "raw" clinical scenarios as a use case repository for use by others.*

The activity of identifying and refining high-level clinical scenarios, in order to lay the foundation for developing technical specifications for medical device interoperability, began in 2005 and is ongoing. The clinical use case scenarios we have collected have been used in many contexts, e.g. seven representative use cases were included in Annex B of the ICE standard, Part I [3], several have been published [5], and use cases on medical device interoperability were included in those provided to the American Health Information Community 2.0 for their 2009 agenda. The incorporation into the ICE standard of clinical use case scenarios in which patient care could be improved by interoperability and system integration has been essential to the progress of the standard, and has demonstrated the value of providing such cases to the research development community.

An important milestone reached in October 2008 was the initiation of the ICE-PAC working group, which has been meeting bi-monthly to perform a gap analysis of the ability of the IEEE 11073 standards to meet the use cases included in the ICE standard. The detailed workflow and requirements for the PCA use case have been completed, and analysis of the x-ray/ventilator use case is underway. This effort, led by DocBox Inc., involves multiple companies (including Philips) in conducting the analysis, and has already yielded important understanding of the capabilities and limitations of the existing 11073 set of standards.

In addition, a primary contribution that our program is making to both our industry partners (SBIRs) and university collaborators (see **Objective 10**) is selecting and tailoring appropriate use cases for their MD PnP-related research and development. Our collaborators have requested that more such scenarios be made available, an activity that is primarily limited by bandwidth at present. We currently have a good repository of about 100 high-level clinical scenarios. However, resource constraints have limited our ability to carry out the necessary analysis, categorization, and amplification to make our database of use cases a sharable resource. This is still an important program goal, as we regularly receive input that these use cases are perceived as one of the program’s assets. We want to make certain that whatever we release to the collaborator community is both usable and useful. We plan to address this need under the new BAA that is pending from TATRC.

Objective 6: A*pply our use case / clinical requirements analysis methodology to the PCA use case.*

Application of our clinical requirements methodology has been done as part of the work on the PCA use case over the past two years. A manuscript describing this methodology is being prepared for publication.

Objective 7: *Elicit clinical scenarios from DoD clinicians and from Boston-area nurses.*

In agreement with our TATRC program officer, we deferred scheduling additional focus groups, since our work has not been limited by a lack of use cases and we are still refining our methodology for analyzing previously collected clinical requirements.

Program Development and Management

Objective 8: *Build collaborations with additional interoperability-focused organizations.*

Our successful approach to convening and facilitating diverse MD PnP stakeholders has been a key part of the program, as evidenced by the continued growth in our collaborations with groups interested in achieving medical device interoperability.

The role of CIMIT in convening and facilitation has made it an important docking point for the MD PnP program. In 2007 CIMIT gave increased visibility to the program, naming Dr. Goldman as the CIMIT Director of Interoperability, and CIMIT has provided program leader funding for the past two years.

Significant milestones were achieved in the past year related to medical society endorsements of medical device interoperability, new sharable contracting language for procurement of interoperable devices, and visibility to those working on health IT at the national level.

Society endorsements. Beginning in March 2007, the need for medical device interoperability has been endorsed by seven clinical societies to date – the Anesthesia Patient Safety Foundation, the American Society of Anesthesiologists, the Society of American Gastrointestinal Endoscopic Surgeons, the World Federation of Societies of Anaesthesiologists, the Society for Technology in Anesthesia, and most recently the American Medical Association and the Massachusetts Medical Society:

> *"RESOLVED, That our American Medical Association (AMA) believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation."*

Healthcare Delivery Organizations. As a result of collaboration with the MD PnP program, Kaiser Permanente in 2006 began to include limited requirements for medical device interoperability in vendor contracts. Under the leadership of MD PnP, two additional major Healthcare Delivery Organizations (HDOs) – MGH / Partners HealthCare and Johns Hopkins Medicine – became actively engaged in this effort in 2008 with the goal of expanding and strengthening the original language to make it clear that customers want this capability and expect vendors to cooperate in making it happen. In October 2008 these institutions issued a nationwide Call to Action to HDOs to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. [6] This collaboration produced sample RFP and contracting language that is being shared with other institutions as well as device manufacturers (MD FIRE: Medical Device Free Interoperability Requirements for the Enterprise) [7] and is available through our program web site (www.mdpnp.org). Dr. Goldman was invited to speak about MD FIRE in a March 2009 web cast at the VHA (Volunteer Hospital Association) that was heard by more than 140 hospitals.

National health IT agenda. Our ties with the Office of the National Coordinator for Health IT**,** NSF, and NIST were strengthened during 2008-2009, as Dr. Goldman was invited to participate in meetings on the National Health Information Network (NHIN) and on the NSF Cyber Physical Systems program (including a luncheon briefing to Congressional staff on Capitol Hill), and he gave a briefing to four divisions at NIST. Dr. Goldman gave a briefing on the MD PnP program to the White House Homeland Security Council in December 2008. He was invited back for subsequent briefings from January to April 2009, and has been working with a group of federal agencies convened by the White House Homeland Security Council to develop an interagency approach to the Medical Public Health Information Sharing Environment (MPHISE), which includes consideration of medical device interoperability requirements. This increased visibility at the national level has been a very positive development for furthering program aims.

NSF projects. As a result of connections made at our June 2007 joint High Confidence Medical Devices, Software & Systems (HCMDSS) / MD PnP workshop [8], we collaborated with computer science and engineering teams at the University of Pennsylvania and the University of Illinois / Urbana-Champaign on proposals to NSF that received three-year grants beginning in September 2008 (see **Objective 10**). These projects are using the concepts and tools of high confidence software development to examine the role of system architecture in safety-critical systems as applied to medical device plug-and-play. At the request of the NSF Cyber Physical Systems (CPS) program, we also worked with the University of Pennsylvania to plan our Second Joint Workshop on High Confidence Medical Devices, Software & Systems / Medical Device PnP Interoperability – which was scheduled as a one-day workshop as part of the NSF-funded Cyber Physical Systems conference (CPSWeek) in San Francisco in April 2009 (see Appendix 7 for agenda). There were about 25 participants, many of whom reported on work they are doing with application of the ICE standard. Several clinicians joined the group in an evening session that was held to facilitate understanding of the clinical need for medical device interoperability.

Figure 3. Clinical Session at Second Joint Workshop on High Confidence Medical Devices, Software & Systems / Medical Device PnP Interoperability, April 2009

ICE-PIC. Over the two years since our last major plenary meeting in June 2007, the MD PnP program has formed collaborations with academic groups funded by NSF and with companies funded by DoD SBIRs/STTRs to work on projects related to medical device interoperability and to the ICE standard in particular. Collaborative relationships with federal agencies have grown, and now include TATRC, the U.S. FDA, NSF, NIST (National Institute of Standards & Technology), and the Veterans Administration. There has been extensive work on developing the ICE standard, and the ICE-PAC gap analysis is underway, including participation by several device manufacturers. In order to facilitate synergistic progress and accelerate our mutual objectives, the MD PnP program organized a two-day workshop of these collaborators (called the ICE-PIC – ICE Platform Integration Collaboration) on July 30-31 2009 (see Appendix 8 for agenda and preliminary report).

The 40 participants represented four universities, three healthcare delivery systems, nine companies, and three federal agencies. They included clinical users, biomedical engineers, information systems engineers, federal regulators and program managers, medical device manufacturers, and standards experts. They presented their project work, shared their vision and ideas, and worked together on a plan for future collaborative activities to advance the ICE standard and development of an open ICE research platform.

DoD Hospital of the Future. At the request of both CIMIT and TATRC, Dr. Goldman became involved in 2008 in the DoD Health Facilities Planning Agency's Hospital of the Future program, and he has been working with Moberg Research, LiveData Inc., and DocBox Inc. to collaborate on making medical device interoperability part of that vision.

Continua Health Alliance. During 2008-2009 Dr. Goldman's ongoing work with the Continua Health Alliance (over 200 companies and hospitals), as chair of the Use Case Working Group, has kept MD PnP goals "in sight" for this important telehealth initiative and has provided valuable learning for the MD PnP program.

Objective 9: *Develop a list of planned MD PnP Lab capabilities for fee-for-service use; submit an NIH/NIBIB Center or Program Grant focused on utilizing the MD PnP program and lab as a national resource for medical device interoperability.*

The concept of the MD PnP "sandbox" Lab has been a key component of the MD PnP vision, and making the Lab operational in 2006 provided a physical anchoring point for the program and enabled the implementation of use case demonstrations to illustrate the concepts and feasibility of MD PnP. Partners HealthCare Information Systems engineers provided a "virtual medical network" infrastructure to support multiple devices and a test environment, but substantial additional funding to hire engineering staff is necessary to realize the potential of the Lab as a vendor-neutral environment for testing and collaboration. This potential was demonstrated during the June 2007 HCMDSS / MD PnP Workshop, when nine interoperability-related demos were brought in by industry and academic institutions.

Work in the Lab to date has been done primarily by graduate students implementing use case demonstrations. We have had discussions with the Continua Health Alliance and with the Patient Care Devices group of the HIMSS IHE organization (Integrating the Healthcare Enterprise) regarding using our lab for device interoperability demonstrations and testing. We have explored a potential membership model for industry, but cannot put it in place until there is adequate staffing. It has become clear over time that it is vital to the success of the MD PnP program that it remain independent and clinically-driven and not be overly influenced by industry, so this independence must be preserved in any industry participation model. We are also considering the feasibility of a provider-driven model, as has been successfully demonstrated by Kaiser Permanente and Continua. CIMIT may be a suitable organization to host such an alliance.

As a result of a contact made at the HCMDSS / MD PnP workshop in June 2007, we investigated the feasibility of applying for a National Resource Center grant from the National Institute of Biomedical Imaging and Bioengineering (NIBIB). Such a center grant appears to be an appropriate pathway for realizing the potential of the MD PnP Program and Lab as a national resource, and such funding would enable a reasonable division of support between TATRC, NIH, and other key supporters. However, the level of effort required for a proposal of this magnitude and requirements is beyond our current resources. We will continue to investigate potential sources of program or center level funding at agencies such as NSF and NIH.

As part of the NIBIB exploration, as well as at the ICE-PIC workshop, we began defining the types of services the Lab would need to provide. This will continue to be a topic of discussion.

Objective 10: *Create multi-year phased program and project plans.*

Core program support for Dr. Goldman and the program manager has depended primarily on funding from TATRC and from Partners HealthCare Information Systems. We have been able to get modest funding through subcontracts on collaborator grants and small project grants, but the constant quest for funding diverts resources from getting program work done. An important goal is to obtain multi-year, long-term sustainable program funding, and it needs to be large enough to assemble a critical mass team of engineers.

Our first multi-year funding for MD PnP has come from the three-year grants awarded by the NSF Cyber Physical Systems Program to investigator groups at the University of Pennsylvania and at the University of Illinois / Urbana-Champaign. MGH/CIMIT is a subcontractor on these projects, and our level of funding is not enough to hire engineers. Similarly, the MD PnP program has been a subcontractor on multiple SBIR awards, which does advance the understanding of the ICE standard and the work of our program, but generates insufficient funding to hire engineers.

In an attempt to identify appropriate long-term funding, we further developed the concept of providing an open ICE-compliant research platform through a white paper, which has been circulated to several federal agencies (FDA, NSF, NIST) and the DoD (TATRC, Office of Health Affairs, DARPA). This white paper describes a two-to-seven-year plan. To date there have been no official responses.

In parallel this white paper has been circulated within the White House Homeland Security Council and MPHISE, as a result of the briefings Dr. Goldman has given to that group and their considerable interest in trying to mount an interagency effort to promote the adoption of and benefit from medical device interoperability.

At TATRC's request, we submitted a new BAA application that includes multi-year phased program plans. We submitted an application for an NIH Challenge Grant in April 2009 (not funded), and also worked on an NIH Grand Opportunity application, which was not submitted on advice from NIBIB. Although many agencies agree that this is important work, it is not yet apparent who can or will fund it.

Regulatory Pathway

Our relationship with the FDA has become stronger over the past two years, as more FDA staff have come to understand the significance of medical device interoperability and the importance of being involved. There are now several internal FDA projects related to device interoperability, and FDA has continued to commit time from an engineer as a senior advisor to our program. We are currently working with the FDA and the Continua Health Alliance on a workshop on medical device interoperability to be hosted by FDA and held in early 2010.

Key Research Accomplishments for Phase II

- Part I of the multi-part ICE standard (Integrated Clinical Environment) was re-worked to address concerns that had been raised by its earlier version, and the improved draft standard passed ballot in ASTM International in March 2009 and is being published by ASTM in Q3 2009.

- Under MD PnP leadership, Kaiser Permanente, MGH/Partners HealthCare, and Johns Hopkins Medicine collaborated to issue a nationwide Call to Action to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes, in a document that contains sample RFP and contracting language that is being shared with other institutions as well as device manufacturers (MD FIRE: Medical Device Free Interoperability Requirements for the Enterprise).

- Since March 2007 the need for medical device interoperability has been endorsed by seven clinical societies to date: the Anesthesia Patient Safety Foundation, the American Society of Anesthesiologists, the Society of American Gastrointestinal Endoscopic Surgeons, the World Federation of Societies of Anaesthesiologists, the Society for Technology in Anesthesia, and most recently the American Medical Association and the Massachusetts Medical Society.

- At the invitation of Dr. S. Ward Casscells, we submitted a white paper in August 2008 via TATRC to the DoD Office of Health Affairs that outlines a seven-year vision and plan for medical device interoperability. An updated version was resubmitted in October, at the request of the FDA Commissioner, Dr. Andrew von Eschenbach. This document has been circulated within several agencies as a reasonably detailed overview of what we believe needs to happen to achieve interoperability.

- We developed and demonstrated scientific exhibits on interoperability use cases at three major conferences in 2008: HIMSS08, the 2008 annual meeting of the American Society of Anesthesiologists (ASA), and the 2008 CIMIT Innovation Congress, at two major conferences in 2009 (HIMSS09 and ATA2009), and at the TATRC Advanced Technology Exposition in June 2009.

- Awareness of the MD PnP program that resulted from our Joint Workshop on High Confidence Medical Devices, Software, & Systems (HCMDSS) and MD PnP Interoperability, held in June 2007, led to new collaborations with the Universities of Pennsylvania and Illinois / Urbana-Champaign. The Cyber Physical Systems program at NSF has funded each of them for three-year projects to work with our program to investigate safety-critical aspects of networked medical device systems.

- The CIMIT MD PnP Lab has been used by our university collaborators to further develop demonstrations of interoperability-based patient safety improvements (improving the safety and quality of portable x-rays and of patient-controlled analgesia systems that are used for pain management). Plans are underway to use the Lab for the NSF projects above and for an internally funded (Information Systems) project on smart alarms.

- We worked with LiveData, Inc. on a U.S. Army SBIR project based on our earlier MD PnP work, and we collaborated with three companies on U.S. Army Phase I SBIRs to develop an ICE supervisor for trauma response.

- We published an article about the MD PnP program in the January-February 2008 issue of *Patient Safety & Quality Healthcare*, and this issue was widely distributed at HIMSS08. Additional articles about the MD PnP work appeared during 2008 in *Anesthesia & Analgesia, Anesthesiology News, Mass High Tech*, and *The Boston Globe*. We published an article about MD FIRE in the January-February 2009 issue of *Patient Safety & Quality Healthcare*, and this issue was also widely distributed at HIMSS09.

- New relationships were formed with NIST, which included a briefing to four divisions in December 2008 and agreement to pursue a collaboration plan, and with the White House Homeland Security Council, which included five briefings from December 2008 to April 2009 to a federal interagency group convened to explore a pathway for medical device interoperability as a critical part of a health information sharing environment.

- At our 2007 HCMDSS / MD PnP joint workshop, the FDA issued a position statement in support of medical device interoperability, which was published in the Proceedings of the meeting. [9]

- We held the first workshop of active MD PnP collaborators in July 2009 – the ICE-PIC (ICE Platform Integration Coordination), which brought together 40 of the MD PnP community to share project information and ideas and to work on plans for future collaboration to further our mutual objectives in achieving medical device interoperability.

In addition to the specific achievements above, the MD PnP program has in the past year-and-a-half gained increasing traction through our collaborative relationships. The web of connections among people in our community of interest continues to generate new connections to supportive individuals in government agencies, healthcare institutions, and other organizations who are helping to further the aims of the program. CIMIT continues to provide space for the MD PnP program for both the Lab and for offices.

Reportable Outcomes

40 Meetings:

- January 13-15 2008 – ICE meeting at CIMIT (9 participants) to address comments made on NWIP submission of Part I to ISO/IEC
- February 2008 – several meetings with Moberg Research, LiveData, DocBox, and TATRC to discuss collaboration on Hospital of the Future efforts
- February 15 & March 14 2008 – TATRC National Forum Tiger Teams meetings (via telephone) to prepare for sessions at National Forum on the Future of the Defense Health Information System in March
- March 4 2008 – MD PnP panel at World Congress of Anesthesia in South Africa
- March 25 2008 – ICE standard discussion with interested parties, hosted by FDA
- March 26-28 2008 – National Forum on the Future of the Defense Health Information System, Washington DC
- May 5-9 2008 – ASTM F29.21 Committee meeting at ASTM to work on ICE standard
- May 29 2008 – phone conference to kick off multi-institutional collaboration on interoperability contract language
- June 19 and 26 2008 – MD MP3™ project team meetings via phone conference
- July 14-16 2008 – ASTM F29.21 Committee meeting at CIMIT to work on ICE standard
- Sept 15-19 2008 – ASTM F29.21 Committee meeting at CIMIT to complete Part I of ICE standard
- Sept 23 2008 – AHIC meeting to show a demonstration of the National Health Information Network (NHIN); Dr. Goldman was able to spend time with both ONC staff and staff from TATRC and the Office of Health Affairs for DoD
- July–October 2008 – twelve team meetings via phone conference with the hospital collaborative working group on interoperability contracting requirements
- October 21 2008 – visit to Massachusetts General Hospital by the FDA Commissioner, Dr. Andrew von Eschenbach, hosted by Dr. Goldman; included a meeting specifically to discuss the MD PnP program and efforts
- December 12 2008 at NIST (National Institute of Standards & Technology), Washington, DC – briefing and agreement to pursue a collaborative plan
- December 15 2008 at DARPA, Washington, DC – discussion of white paper drafted for Dr. Casscells
- December 16 2008 at the White House Executive Office Building, Washington, DC – briefing for White House Homeland Security Council
- January 6 & 21 2009 – meetings with Moberg Research and DocBox Inc. to discuss collaboration around ICE-compliant development
- January 9, February 26, and March 24 2009 – briefings to the White House Homeland Security Council as part of the development of a public health information-sharing program.
- January 22 2009 – meeting with LiveData to discuss ICE-compliant device modeling

- February 27 2009 – meeting with LTC Steven Steffenson at TATRC
- March 3-4 2009 – LiveData ICE Manager Phase II SBIR kick-off meeting (and pre-meeting)
- March 4 2009 – meeting with CTO of GE Healthcare regarding interoperability
- March 19 2009 – interoperability discussion with the Brigham & Women's Hospital AMIGO project
- March 23-24 2009 – meetings with NIST and with the Federal Health Architecture head at the office of the National Coordinator for Health IT, Washington DC
- April 1-2 2009 – White House Homeland Security Council Biodefense Directorate Conference – ongoing discussions with interagency group
- April 4-8 2009 – scientific exhibit on PCA safety at HIMSS09 (Healthcare Information & Management Systems Society annual conference), Chicago, IL
- April 16 2009 – Second Joint Workshop on High Confidence Medical Devices, Software & Systems / Medical Device PnP Interoperability, held as part of the NSF-sponsored CPSWeek, San Francisco, CA
- April 17 2009 – working meeting with Linea Research (DoD SBIR Phase I grant recipient for ICE supervisor), Palo Alto, CA
- April 26-29 2009 – scientific exhibit on PCA safety in TATRC booth at ATA09 (American Telemedicine Association), Las Vegas, NV
- May 18-22 2009 – ASTM Committee F29 International standards meeting, including ICE discussions, Vancouver, CAN
- May 26 2009 – meeting of CDC Board of Scientific Counselors, National Center for Public Health Informatics, Orlando, FL
- June 8-12 2009 – ISO/IEC Technical Committee 121 standards meeting (Dr. Goldman is chair designate)
- June 16-18 2009 – scientific exhibit on PCA safety at TATRC Advanced Medical Technology Exposition at its OASIS facility, Ft. Detrick, MD
- July 30-31 2009 – ICE-PIC (ICE Platform Integration Coordination) workshop of MD PnP active collaborators, convened at CIMIT, Cambridge, MA

36 MD PnP Presentations:

Dr. Goldman delivered invited presentations on Medical Device Interoperability for Improving Patient Safety and Healthcare Efficiency to the following groups during the past year-and-a-half:

- January 17-18 2008 at the Society for Technology in Anesthesia annual meeting, San Diego, CA – Dr. Goldman moderated a panel on "Designing Operating Rooms for Today" and gave a talk on "Update on Interoperability Healthcare Initiatives"
- January 25 2008 at the ISO Technical Committee 121, Subcommittee 2 meeting, London, ENGLAND – this talk on "Airway Laser Safety" was centered on one of the use cases collected by the MD PnP program
- February 5 2008 at the Veterans Affairs Enterprise Architecture Open Management Meeting, Grand Junction, CO
- March 4 2008 at the World Congress of Anesthesia in South Africa – Dr. Goldman chaired an MD PnP panel session
- March 27 2008 at the National Forum on the Future of the Defense Health Information System, Washington DC
- April 1-2 2008 at The Johns Hopkins Hospital, Baltimore, MD – Dr. Goldman spoke to a group of clinicians on April 1st and gave a talk on April 2nd to engineers at a seminar at the NSF Engineering Research Center for Computer-Integrated Surgical Systems & Technology
- April 5 2008 at "TATRC Day" at the American Telemedicine Association (ATA), Seattle, WA

- April 25 2008 at the Tokyo Women's Medical University, Tokyo, JAPAN – Dr. Goldman gave the keynote address to the Japan Association for Clinical Monitoring
- May 20 2008 at the GSA & NSF-sponsored Collaborative Expedition Workshop, Arlington, VA
- May 28 2008 at Anesthesia Grand Rounds at Brigham & Women's Hospital, Boston, MA
- May 30 2008 at the TiECON (entrepreneurship) East conference, Waltham, MA
- October 21 2008 for the FDA Commissioner, Dr. Andrew von Eschenbach, during his visit to Massachusetts General Hospital, Boston, MA
- October 29 2008 at the CIMIT Innovation Congress 2008, Boston, MA
- November 14 2008 at a workshop on "Wireless Technologies in Hospital Health Care" hosted by Polytechnic Institute of New York University, New York City, NY
- December 2 2008 for the Danish Patient Safety Initiative, Copenhagen, DENMARK
- December 5 2008 at the MIT MTL (Microsystems Technology Laboratories) workshop on "Next-Generation Electronic Medical Systems", Cambridge, MA
- December 12 2008 at NIST (National Institute of Standards & Technology), Washington, DC
- December 15 2008 at the NSF Cyber Physical Systems Program Information Day, Washington, DC
- December 16 2008 to the White House Homeland Security Council, Washington, DC
- January 15 2009 at the Society for Technology in Anesthesia (STA) annual meeting, Orlando, FL
- January 9, February 26, and March 24 2009 briefings at the White House Executive Office Building for interagency group convened by Homeland Security Council
- January 20 2009 for CIMIT leadership
- March 18 2009 web cast at VHA (Volunteer Hospital Association) on MD FIRE (shared contracting language) heard by more than 140 hospitals
- April 2 2009 at the White House Homeland Security Council Biodefense Directorate Conference, Washington DC
- April 14 2009 at the 6th World Health Care Congress, Health IT Summit Panel, Washington DC
- April 16 2009 at the Second Joint Workshop on High Confidence Medical Devices, Software & Systems / Medical Device PnP Interoperability, held as part of the NSF-sponsored CPSWeek, San Francisco, CA
- April 26 2009 at the TATRC Hospital of the Future meeting, held at ATA09 (American Telemedicine Association), Las Vegas, NV
- April 28 2009 at the Engineering Society of Detroit conference on "Accelerating Innovation", sponsored by INCOSE (International Council on Systems Engineering)
- May 19 2009 at the American Thoracic Society meeting, San Diego, CA
- June 23 2009 at the AdvaMed Chief Technical and Scientific Officers meeting, Washington DC
- July 9 2009 at the NSF Cyber Physical Systems luncheon briefing for Congressional staff, Capitol Hill, Washington DC

Web Site:

- The MD PnP web site (www.mdpnp.org) is maintained as a major communication vehicle for the program – it provides access to the ICE standard, the MD FIRE contracting language, MD PnP publications, posters, and slides, as well as links to streaming video of talks from our plenary meetings.
- The MD PnP program has used project collaboration web sites available through Basecamp to facilitate communication regarding specific projects, e.g. MD MP3™ and most recently the ICE-PIC group.

Manuscripts/Publications 2008-2009:

- Lesh K, Weininger S, Goldman JM, Wilson B, Himes G, "Medical Device Interoperability – Assessing the Environment," *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007)*, *Cambridge, MA, June 25-27, 2007*, pp. 3-12. IEEE Computer Society Press, 2008.
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Funding Applications facilitated by this BAA (total costs shown):

- Funded: CIMIT: $70K for FY07 core support of the PI and Program Manager
- Funded: Partners Healthcare IS: $57.5K for FY06-07 support for MD PnP Lab
- Funded: Partners Healthcare IS Research Council: $85,675 for Developing Formal Requirements-Engineering Methodology in Support of the MD PnP Program
- Funded: Partners Healthcare IS: $115K for FY07 for MD PnP Program Support
- Funded: TATRC: $34.8K for HCMDSS / MD PnP Joint Workshop

- Funded: NSF: $49.9K for HCMDSS / MD PnP Joint Workshop
- Funded: TATRC: $48.6K for MD PnP subcontracts on LiveData SBIR Phase I and II awards
- Funded: Partners HealthCare IS: $115K for FY08 for MD PnP Program Support
- Funded: CIMIT: $105K for FY08 support for prototype development of a PCA application of the Medical Device PnP Platform™ (MD MP3™)
- Funded: CIMIT: $18.9K for FY08 program leader support
- Funded: Partners Healthcare IS Research Council: $115K for Closed-Loop Clinical Alert Annunciation
- Funded: Partners HealthCare IS: $50K for FY09 for MD PnP Program Support
- Funded: CIMIT: $50K for FY09 program leader support
- Funded: NSF: $210K for MGH subcontract on University of Pennsylvania award
- Funded: NSF: $212K for MGH subcontract on University of Illinois / Urbana-Champaign award
- Funded: TATRC: $15.5K for MGH subcontract on Moberg Research SBIR award
- Funded: TATRC: $15.5K for MGH subcontract on Linea Research SBIR award
- Funded: TATRC: $15.5K for MGH subcontract on GCAS SBIR award

In-kind engineering support and/or contribution of equipment for the MD PnP lab have been provided by several academic and industry partners.

Conclusion

This BAA has provided core program support to develop and extend key capabilities of the Medical Device “Plug-and-Play” (MD PnP) Interoperability Program to lead the evaluation and adoption of open standards and technology for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency. The majority of this BAA has funded core personnel, providing the time to identify and access numerous other resources and to build collaborations to achieve the BAA objectives.

Notable achievements enabled or facilitated by this TATRC support include:

- A medical device interoperability lab was created at CIMIT in Cambridge, MA as a multi-institutional, interdisciplinary shared resource
- Clinical use case demonstrations showing the capability of medical device interoperability to improve patient safety have been developed and exhibited at six national meetings
- An international standard (ICE) describing the functional architecture and risk mitigation strategies for networked patient-centric interoperable medical devices was created, submitted to ISO/IEC as a New Work Item Proposal, then rewritten and submitted to ASTM, where it passed ballot and is being published
- An international conference on “Improving Patient Safety through Medical Device Interoperability and High Confidence Software” was held, with a follow-up workshop
- Three major healthcare delivery systems collaborated on shared interoperability contracting language under MD PnP program leadership
- Seven medical societies to date have endorsed the need for medical device interoperability to improve patient safety
- New collaborations were established with federal agencies, including NIST and the White House Homeland Security Council
- An invited white paper with a clearly articulated implementation pathway was provided to TATRC and the DoD Office of Health Affairs, the FDA Commissioner, DARPA, and the White House Homeland Security Council
- A workshop of collaborators working on ICE-related development projects was convened

These activities are highly interdependent and synergistic, and TATRC support has been instrumental in providing the “program glue” to effectively leverage these synergies to move substantially closer to the achievement of medical device interoperability. The potential impact on patient safety is significant.

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Appendices

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MD FIRE Document – October 2008
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MD PnP White Paper – July 2009

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MEDICAL DEVICE PLUG-AND-PLAY

REAL-TIME LOCATION SYSTEMS

E-PRESCRIBING: SAFETY AND WORKFLOW

CRM TO SUPPORT BEST PRACTICES

CLINICAL VIGILANCE

The OR of the Future at Massachusetts General Hospital in Boston includes a wide array of medical devices.

Photo courtesy of Julian Goldman

GETTING CONNECTED for PATIENT

By Susan F. Whitehead and Julian M. Goldman, MD

Medical devices are essential for the practice of modern medicine. However, unlike the inter-connected "plug-and-play" world of modern computers and consumer electronics, most medical devices used for the care of high-acuity patients are designed to operate independently and do not employ open networking standards for data communication or for device control.

For years we have benefited from integrated systems to enhance the safety of potentially hazardous activities. For example, safety interlocks that require stepping on the brake before putting your car in gear, or having a clear alarm sound in the cockpit if the landing gear are not deployed when a plane descends for a landing, add "error resistance" to potentially hazardous equipment. But, the means is not yet available to easily achieve cross-vendor device integration to implement error resistance in operating rooms (ORs) and other clinical environments today.

How could systems be made more error resistant? Consider, for example, the case of an anesthetized 32-year-old woman having routine gall bladder surgery, who had an x-ray taken during the procedure while her breathing was being supported by a ventilator. Such x-rays are common, and they require that the ventilator be turned off temporarily in order to minimize blurring of the image due to chest movement. In this case, however, the anesthesiologist became distracted by another problem in the OR and forgot to turn the ventilator back on, resulting in the patient's death. If the x-ray and ventilator were connected, the timing of the image could be automatically synchronized with respiration, so that the ventilator need not be stopped. This seems like a simple enough solution, yet we do not have this available today.

Given sufficient resources, a hospital engineering group could interconnect the ventilator and x-ray, but "one-off" connections are complicated and expensive, and may be unreliable. In contrast, "plug-and-play" connectivity to integrate consumer electronics is commonplace today. Our consumer products rely on the ease and simplicity of standards-based plug-and-play to allow consumers to transfer digital photos, send email, use USB memory sticks, connect a Bluetooth headset, or interconnect home audio and video equipment.

The adoption of appropriately robust connectivity standards and technologies by healthcare will enable the plug-and-play integration of medical devices. The integration of individual medical devices into a networked system for the care of a high-acuity patient will support an infrastructure for innovation in patient safety, treatment efficacy, and workflow efficiency. A system of integrated medical devices can reduce medical errors and healthcare costs to the benefit of patients throughout the continuum of care by enabling development of:

- Medical device safety interlocks to produce error-resistant systems.
- Clinical decision support requiring real-time integrated clinical parameters and procedural context.
- Enhanced sensitivity and specificity of clinical alarm systems through the integration of physiological measurements, equipment status, and contextual information.
- Monitoring of device activity and performance.
- Automated system readiness assessment (prior to starting invasive clinical procedures).
- Support of remote-ICU surveillance and quality improvements.
- "Plug-and-play" modularity to support "hot swapping" of "best of breed" devices.
- Physiologic closed-loop control, e.g. of medication, fluid delivery, and ventilation.
- Real-time inventory of equipment for asset tracking, maintenance, upgrade, recall, and readiness assessment.
- Comprehensive data collection (like a "flight recorder") for the analysis of near-misses and adverse events.

The importance of applying modern systems engineering solutions, such as interoperability, to improve patient safety and reduce costs was addressed in a National Academy of Sciences report (2005) entitled *Building a Better Delivery System: A New Engineering/Health Care Partnership*. However, cross-vendor

SAFETY

How Medical Device "Plug-and-Play" Interoperability Can Make a Difference

standards-based interoperability has not been widely adopted for medical devices. Therefore, when device integration is required, customized device interfaces must be developed, which, in addition to increased costs and development time, are unlikely to provide needed functionality.

In October 2006, the Anesthesia Patient Safety Foundation (APSF) held a workshop to assess the safety of patient-controlled analgesia (PCA) and solutions to decrease associated adverse events, especially medication overdose. As part of the solution strategy, the APSF identified ways in which medical device interoperability could facilitate a solution. Subsequently, the APSF Executive Committee issued a statement of support for interoperability requirements in March 2007:

> APSF believes that intercommunication and interoperability of devices could lead to important advances in patient safety, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind….
> APSF also recognizes that as in all technologies for patient safety, interoperability poses safety and medicolegal challenges as well. Development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety and outcome benefit (Weinger, 2007).

Medical Device "Plug-and-Play" Interoperability Program

The Medical Device "Plug-and-Play" (MD PnP) Interoperability Program was established in 2004 to lead the adoption of open standards and technology for medical device interoperability to support clinical innovation. The term "PnP" was adopted because the required technology infrastructure has many elements in common with the plug-and-play approach used in other computer-based systems. The program is affiliated with Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare Information Systems, with additional support from TATRC (U.S. Army Telemedicine & Advanced Technology Research Center). Having evolved from the OR of the Future program at MGH, the MD PnP program remains clinically grounded. The program has been convening diverse stakeholder groups (clinicians, biomedical and clinical engineers, healthcare delivery systems, regulatory agencies, medical device vendors, standards development experts) to learn from past efforts to develop medical device interoperability solutions, to harmonize with current synergistic programs, and to elicit clinical scenarios for "improving healthcare through interoperability." Since the program's inception, more than 600 clinical and engineering experts, and representatives of more than 85 institutions that share a vision of medical device interoperability have participated in ongoing convening activities.

To date, the MD PnP program has convened four plenary meetings to bring stakeholders together for information exchange and discussion of issues related to achieving medical device interoperability. The FDA hosted the second meeting so that regulatory issues could be more thoroughly explored with increased FDA participation.

The most recent plenary meeting was the Joint HCMDSS[1] / MD PnP Workshop held in June 2007, which added academic embedded systems experts to interact with stakeholders, attracting 145 attendees. This workshop brought together two highly synergistic research communities (MD PnP and HCMDSS), included a panel of federal agencies (NIST, NSF, NIH, TATRC, FDA), and had as the opening keynote speaker Dr. Robert Kolodner, the National Coordinator for Health IT, generating a more solid connection with the national health IT agenda.

These plenary meetings have been sponsored jointly by TATRC and CIMIT and by TATRC and NSF through conference grants, and by the FDA. Smaller working group meetings have been held to develop program strategy, to work on clinical requirements methodology, to develop interoperability use-case demonstrations, and to work on standards. Our web site (http://www.mdpnp.org/) has provided online discussion forums and information about the program, including streaming video of the talks from the May 2004, June 2005, and June 2007 plenary meetings.

The concept of medical device interoperability is not new. In fact, there have been several earlier efforts to move in that direction, and we have summarized this history in previous publications (Goldman, et al., 2005; Schrenker, 2006). However, none of these prior efforts has met with broad success. Through our conferences and working group meetings, the MD PnP program has identified several causes for historical failures to achieve widespread adoption of interoperability, including the absence of industry-adopted interoperability standards for data communication and device control, and lack of an appropriate "plug-and-play" system architecture (due to emphasis on proprietary solutions). In addition, there have been regulatory concerns and liability concerns that have to be addressed, the few available use cases have been poorly articulated, and the business case for interoperability often conflicts with single-source and end-to-end solutions. These barriers underscore the need for an integrated clinical environment "ecosystem" that would include system functions such as data logging, data security, device authorization, and connectivity to the hospital information system. These functions would contribute to a complete systems solution that could meet clinical, technical, regulatory, and legal requirements.

CIMIT PnP Lab

The CIMIT MD PnP Lab opened in May 2006 to provide a vendor-neutral "sandbox" to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. This 500-square-foot facility is outfitted with a high-speed virtual medical network provided by Cisco Systems and installed by Partners HealthCare Information Systems, with access to a patient database of mock

[1] *High Confidence Medical Devices, Software, and Systems*

EHRs that can be used for testing. In the Lab, we are working with collaborators on the development of demonstrations of interoperability-based patient safety improvements, e.g. improving the safety and quality of portable x-rays and of patient-controlled analgesia systems that are used for pain management.

We have developed and demonstrated scientific exhibits showing how interoperability could improve patient safety in common use cases, showing these at the 2006 and 2007 annual meetings of the American Society of Anesthesiologists (ASA), at HIMSS07 (the Health IT and Management Systems Society), and at the 2006 and 2007 CIMIT Innovation Congresses. These exhibits include a demonstration of how medical device interoperability could enable automatic synchronization of x-ray exposure with ventilation, so that there is no need to turn off the ventilator to obtain the x-ray, and a demonstration of how continuous monitoring of a patient's SpO_2 and respiratory rate could detect the onset of respiratory depression, and automatically stop the PCA infusion pump, lock out any further doses, and activate the nurse call system. We are currently working on a further variation of the PCA use case demonstration for a scientific exhibit at HIMSS08.

The kinds of resources we are developing in the MD PnP Lab will make it a unique and useful resource for others. A long-term goal of the program is to have the Lab evolve to serve as a national resource for medical device interoperability work.

The MD PnP program has built a multi-disciplinary, multi-institutional team to develop and implement a strategy to address the historical barriers and develop the building blocks or "legos" for interoperability through collaborative projects. Our geographically dispersed team of collaborators includes participants from Kaiser Permanente, the FDA, the University of Pennsylvania, Dräger Medical Systems, Draper Laboratory, LiveData Inc., Mitre, DocBox Inc., the University of New Hampshire, IXXAT, NIST, NSF, and Geisinger Health System, as well as the Partners HealthCare System community (Massachusetts General Hospital Anesthesia, Biomedical Engineering at MGH and Brigham & Women's Hospital, and PHS Information Systems). One of our projects has examined the MD PnP program as a social network, which has evolved over the past 3.5 years from a simple network of 85 people connected primarily to the program leadership, to a larger, complex "smart" network of over 600 people with many connections to each other and who are constantly forming new clusters as they collaborate and bring new people in.

Current Activities

Our primary program activities are centered around clinical requirements, standards work, interoperability contract language, and regulatory issues.

Eliciting high-level clinical scenarios to define user requirements to drive and inform interoperability solutions. The need to start with clinical requirements was identified early by all stakeholder groups as critical to the creation of a clinically valid standardization framework. To gather these clinical requirements, we held several focus group sessions at medical and engineering society meetings, beginning in the first year of the program and then on an ongoing basis. Participants have included anesthesiologists (from the Society for Technology in Anesthesia, and the American Society of Anesthesiologists), surgeons (from the Society of American Gastrointestinal Endoscopic Surgeons), and clinical and biomedical engineers (from the Association of Advanced Medical Instrumentation). Each of these groups brought unique perspectives on what interoperability of medical devices could contribute to patient safety and workflow efficiency in the OR and other high-acuity settings, and on what the "ideal" system should look like and how it should behave. Additional focus groups will be held with nursing staff and DoD clinicians, and we expect to work with collaborators on a web-based tool for collecting clinical scenarios that would benefit from interoperability.

Developing a reliable repository of interoperability use cases that can be shared with other groups. The raw input from focus group sessions was organized into a repository of defined clinical scenarios or "use cases," which were presented back to earlier participants for refinement and then used to elicit feedback from new

At the CIMIT Innovation Congress in November 2007, Dr. Julian Goldman demonstrated how patient safety could be improved by synchronization of the x-ray exposure with the ventilator during surgery.

Photo courtesy of Christopher Bowers

clinical sources. This repository is being further developed in conjunction with the FDA to highlight safety-critical aspects and requirements for interoperability. The use cases in the repository will be used to test interoperability functionality developed by device vendors using standards.

Developing a clinical requirements methodology that enables use case scenarios to be specified at the level of detail needed to derive engineering requirements. As part of our clinical requirements work, we are developing a methodology that incorporates clinical workflow information and also identifies non-clinical requirements (performance, interfaces, functional and "non-functional"). The clinical requirements will be further refined to generate engineering requirements and specifications, which will then inform the identification of candidate systems and standards.

Supporting the implementation of open networking standards to accelerate medical device interoperability. To achieve adoption of a standardization framework for medical device interoperability that has the support and buy-in of industry, there must be an open standards development environment. An independent, vendor-neutral program can act as the catalyst to bring the makers of proprietary software and systems to the table together with their clinical customers and government regulators to achieve this goal. The first step is developing standards for a patient-centric **"Integrated Clinical Environment" (ICE)** to define the ecosystems in which interoperability can be successful.

A collaborative relationship with Draper Laboratory resulted in the participation of several senior Draper engineers, who in June 2006 wrote the preliminary draft of the multi-part ICE standard, which embodies the elements of the overall technology ecosystem needed to safely implement networked medical device systems. In six working group meetings over the past year, we convened engineers and standards experts from Partners HealthCare System, the FDA, Draper Lab, Dräger Medical, Mitre Corporation, and Philips Medical to prepare ICE Part I (network control), which was then submitted by the U.S. Technical Advisory Group in September 2007 into the ISO/IEC international standards development process.

Developing shared contract language to support the preferential acquisition of interoperability standards-conformant systems by healthcare organizations. As a result of collaboration with this program, Kaiser Permanente has since 2006 included the following language in vendor contracts:

> Supplier agrees to participate with Kaiser in the development of a medical device plug and play integration standard (the 'Integration Standard'), and… will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved, Supplier intends to continue… to provide open interfacing protocols…

MD PnP Team Receives Kennedy Award

Photo courtesy of Thomas J. Gustainis

At its annual conference in November 2007, CIMIT named the Medical Device Plug-and- Play team, led by Julian M. Goldman, MD, of Massachusetts General Hospital, as the recipient of CIMIT's annual Edward M. Kennedy Award for Healthcare Innovation. The Kennedy Award was established in 2002 to recognize the exceptional and unique contributions made by interdisciplinary collaborations in bringing technology to health care. It is given each year to recognize an outstanding CIMIT team whose work over the past year embodies the CIMIT mission of collaboration to make a significant difference in healthcare through innovation and technology. The Award honors the Massachusetts senator, who has been a pioneer in healthcare and a tireless supporter of innovation and technology research.

The MD PnP team, which is multidisciplinary and geographically dispersed, is the largest team to receive the award and represents the largest number of collaborative organizations, including the University of Pennsylvania, MITRE Corporation, Kaiser Permanente, Brigham and Women's Hospital, Massachusetts General Hospital, the US Army Telemedicine & Advanced Technology Research Center, Draper Laboratory, DocBox Inc., LiveData Inc., IXXAT USA, Draeger Medical, Philips Medical Systems, the Food and Drug Administration, and CIMIT.

The team is committed to working collaboratively to ensure interoperability of medical devices in the OR and other clinical settings. That means that all devices and electronic systems are linked, so that information is exchanged and mistakes are minimized. "Each year there are accidents and unnecessary deaths in operating rooms," said Dr. Goldman. "Each OR has many kinds of electronic systems, many of which don't interact with each other. One of our key goals is to make sure all medical device systems can communicate, and to create international guidelines so that planners and administrators can create a failsafe hospital infrastructure."

Extending the use of this kind of contract language is a current focus of the MD PnP program. Partners HealthCare is currently considering the use of such language, and other healthcare delivery organizations are increasingly expressing interest.

Defining a safe, "least-burdensome" regulatory pathway for patient-centric networked medical devices, in partnership with the U.S. FDA. An early assumption of this program has been that the goal of medical device interoperability standardization can only be achieved by working closely with the FDA and other regulatory agencies, and this has been our approach to date. The mutual objectives of the FDA and the MD PnP program are to assure patient safety and to identify a regulatory pathway that will support the MD PnP concept, i.e. that will not require re-validation or re-clearance of the entire system as each new independently validated device is added to the MD PnP network.

What is needed for success? Published consensus standards are only one of the ingredients required to achieve interoperability solutions. Other ingredients include the availability of reference implementations of standards such as IEEE 11073 and ICE, interoperability and conformance testing tools, a vendor-neutral testing and evaluation environment (as outlined above), and a safe regulatory pathway. Also, we need a staged implementation plan that recognizes the need to accommodate legacy systems, in order to support widespread adoption of standards-based medical device interoperability.

Today we are seeing a convergence of many factors that are key to success—improved technology, more open-sourcing, technically savvy clinicians, and a willingness on the part of regulatory authorities to consider new validation paradigms. We believe it is now clear that in order for medical device interoperability to become a reality, the following ingredients are required:

- Clinically meaningful, market viable, use cases.
- Open interoperability standards to enable these use cases.
- Reference implementations of the standards and related system architecture.
- Standards profiles or guidelines to describe how to use the standards to achieve interoperability.
- Business conditions that support interoperability.
- Availability of enabling technology.
- Interoperability compliance testing (formal and/or informal).
- Promotion (marketing, education, conferences, evangelists).

How to Participate

One of the greatest strengths of the MD PnP program has been the involvement of collaborators from the many diverse constituencies that have a vested interest in improving patient safety: clinicians, biomedical and clinical engineers, healthcare delivery systems (including hospitals and other high-acuity care settings), regulatory agencies, medical device manufacturers, and interoperability-promoting organizations like IHE, APSF, and medical societies. There are roles that each of these groups can play in making medical device interoperability a reality:

- ***Clinicians*** can contribute clinical scenarios (or "use cases") to ensure that new interoperability standards and technology will enable meaningful clinical solutions. Diversity of use cases should increase the likelihood of effective and generalizable solutions.
- ***Engineers*** can analyze clinical use cases to generate functional specifications, assess current standards to perform gap analyses, and evaluate proposed technologies. Diverse engineering expertise is essential.
- ***Healthcare delivery systems*** can specify performance requirements, and require adherence to medical device interoperability language in vendor contracts. Standards for interoperability will happen only when there is strong consumer demand.
- ***Regulatory agencies*** can create new paradigms for regulatory clearance of interoperable medical devices.
- ***Medical device manufacturers*** can participate in the development and adoption of interoperability standards, and partner with the MD PnP Program to develop a shared interoperability testing environment.
- ***Interoperability promoting organizations*** can support revising existing standards to meet clinical requirements, collaborate on clinical use-case implementations in the MD PnP Lab, and ensure that through collaboration we shepherd the adoption of medical device interoperability to empower innovation in the safety and efficiency of health care.

By engaging in a dialogue with each other about the implementation of interoperability, and by working together collaboratively, these diverse constituencies can ensure the best outcomes for patient safety. Getting connected for patient safety isn't just about the devices – it's also about the collaboration. PSQH

Susan Whitehead *is the program manager of the Medical Device Plug-and-Play (MD PnP) Interoperability program at CIMIT (Center for Integration of Medicine and Innovative Technology), a consortium based at Partners HealthCare in Boston. She coordinates collaborations, communications, and projects for the multi-disciplinary, multi-institutional MD PnP program, which includes a growing network of more than 600 individuals and 85 institutions.*

A graduate of Rice University, Ms. Whitehead has worked with computer applications in healthcare settings during most of her career, primarily for Bolt Beranek and Newman Inc. (BBN) in Cambridge, MA. At BBN she managed a major project (CLINFO) that provided NIH-sponsored General Clinical Research Centers with a time-oriented clinical database designed for research, and coordinated other projects ranging from information commerce in a multi-practice clinic to evaluation of the NIH Division of Research Resources by a multidisciplinary panel of experts. She also managed a Technical Support group for BBN Software Systems, and led and trained TQM quality improvement teams at BBN and at PictureTel Inc. Prior to joining CIMIT, Whitehead managed research operations for the Digital/Compaq/Hewlett Packard East Coast research lab. She recently moved from industry into the healthcare sector in order to pursue her interest in applying technology to healthcare information. Whitehead may be contacted at swhitehead@partners.org.

Julian Goldman *is director of the program on Interoperability at CIMIT (Center for Integration of Medicine and Innovative Technology), a practicing anesthesiologist in the Massachusetts General Hospital (MGH) "OR of the Future," and a physician advisor to Partners HealthCare Biomedical Engineering at MGH. He is the director of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program, which he founded in 2004 to lead the adoption of open standards and technology for networking medical devices to support high-acuity clinical solutions for improving patient safety and healthcare efficiency.*

Goldman received his MD from SUNY Downstate Medical Center in New York, and performed anesthesiology residency and research fellowship training at the University of Colorado School of Medicine in Denver. He departed the University of Colorado as a tenured

The MD PnP clinical requirements working group discusses collaborative projects. Shown are (left to right): Tracy Rausch (DocBox Inc.), Rob McCready (Mitre Corporation), Heidi Perry (Draper Laboratory), Shankar Krishnan and Philippe Cortes (Mass General Hospital Biomedical Engineering), Bill Weinstein (Draper), Harry Sleeper (Mitre).

Photo courtesy of Julian Goldman

associate professor to work as vice president of medical affairs of a medical monitoring company, and joined Harvard Medical School and the Departments of Anesthesia & Critical Care and Biomedical Engineering at MGH in 2002.

Goldman recently served as an officer in the FDA Medical Device Fellowship Program, chairs the Use Case Working Group of the Continua Health Alliance, leads several ASTM, ISO, and IEC medical device standardization activities, and is a founding member and immediate past-president of the Society for Technology in Anesthesia. He may be contacted at www.jgoldman.info.

WANT TO LEARN MORE?

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Medical Device Interoperability for Patient Safety: Driving Procurement Changes	October 2008

Medical Device Plug-and-Play (MD PnP) Program
Massachusetts General Hospital / Partners HealthCare System
Johns Hopkins Medicine
Kaiser Permanente

This paper discusses the requirements for medical device interoperability in the modern healthcare environment. These requirements are changing the way in which we procure medical devices. An appendix provides shareable RFP and contract language examples.

Background

Medical devices, essential for the practice of modern medicine, have been traditionally designed to operate independently using proprietary protocols and interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems no longer provide an acceptable solution. Medical devices and systems must easily integrate with other vendors' equipment, software and systems in order to improve patient safety.

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and systems.[1] Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency". [2][3]

Our collaboration through the Medical Device Plug-and-Play (MD PnP) program over the last four years leads us to conclude that Healthcare Delivery Organizations (HDOs) must lead a nationwide call to action for interoperability of medical devices and systems. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.

We HDOs wish to adopt interoperability standards for medical device interconnectivity. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and systems will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; will improve the quality of medical devices; will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; will release HDO resources now used to maintain customized interfaces; and will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual, institutional, and national goals for improved healthcare quality and outcomes. Our goal is to document the clinical demand and to strongly encourage the development and adoption of medical device interoperability standards and related technologies.

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Clinical Context

Why is medical device interoperability necessary to improve patient safety? As an example, when taking an x-ray in the Intensive Care Unit, the ability to synchronize the x-ray with the patient's breathing cycle has been demonstrated to improve image quality. [4] Unfortunately, the capability of interconnecting and synchronizing these devices is not available today. Similarly, a safety interlock that would stop the flow of opioid pain medication from an infusion pump and call the nurse if a patient showed signs of respiratory distress could save lives.[5] There are numerous other examples whereby medical device interoperability and medical system integration, if available, will improve patient safety.[6],[7]

Standards-based medical device interoperability can provide real-time comprehensive population of the electronic medical record (EMR), and in the future will permit the creation of integrated error-resistant medical systems that will support advanced capabilities such as automated system readiness assessment; physiologic closed loop control of medication delivery, ventilation, and fluid delivery; decision support; safety interlocks; monitoring of device performance; plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; and other innovations to improve patient safety, treatment efficacy, and workflow efficiency.[6]

Recommendations

We strongly encourage HDOs to adopt medical device interoperability as an essential element of their procurement process.

We have drafted sample medical device interoperability requirements and would encourage HDOs and vendors to use such requirements in their procurement process, including their requests for proposals (RFPs) and contracts. You can find the sample language attached as an Appendix to this document and available at http://www.mdpnp.org/MD_FIRE.html. We expect that the sample requirements and contracting language will evolve over time based on use.

We believe that changing the way in which we procure medical devices to integrate requirements for interoperability will provide a way for us to ensure patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information.

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Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

RFP AND CONTRACT LANGUAGE EXAMPLES (6 pages)

MD FIRE: RFP EXAMPLES

Note: This is language to be used in an RFP or RFI to select vendors in a competitive process. Include in the RFP the contract terms, i.e. the contract language examples below, if it is the intention of the Customer to utilize them for the contract. Each of the sections below may be included in any combination.

RFP Example A: Request for Specific Functionality and Interoperability Capabilities
Note: Requests a complete description of specific functionality and interoperability capabilities. The text shown is an example only, and should be greatly expanded by the HDO. This may be used if the HDO knows what interoperability capabilities it is seeking, what product functions support that interoperability, and which standards are to be implemented.

- Current Interoperability Functionality: Devices must have the following capabilities:
  - Pulse oximeter sends % oxygen saturation and pulse rate data to other clinical systems using standard [XXXXX].
  - Etc.
- Future Interoperability Functionality: Device must have the following capabilities within [18 months] [of standard XXXXX being approved] [of these functions being included in HITSP interoperability standards]:
  - Pulse oximeter sends clinical and technical (equipment) alarms, and upper and lower oxygen saturation and pulse rate alarm settings to other clinical systems using standard [XXXXX].
  - Pulse oximeter interfaces with clinical systems and accepts data and control to set alarm limits (and averaging time and sensitivity mode, if applicable).
  - Etc.
- Performance testing: All requirements will be verified in the Customer's own test environment and operational environment.
- Support: All functions must be included in the regular maintenance and support agreement.

RFP Example B: Description of All Interoperability Capabilities and Related Functionality
Note: Requests a complete description of the Product interoperability, but does not call for any particular function or standard.

Please include in your response to the proposal your company's approach and plans for interoperability of your Products, specifically:

- All interoperable interface standards, technology standards, terminology standards, communication standards, and design guidelines that the Products will implement and comply with (including but not limited to USB, WiFi, ZigBee, Bluetooth, HL7, Continua). For each standard and guideline, describe:
  - The current and proposed scope of compliance with each standard and guideline, including but not limited to the exact specifications and guideline versions.
  - A description of the current and proposed Product functions that are interoperable and supported by the standards and guidelines.

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  - An estimate of the [NTE, time and materials, estimated] cost and schedule to implement the proposed capabilities and standards listed above. If updates or compliance are included in the regular maintenance agreement, please describe those terms.
    "Current" means functions, features, and compliance that are currently marketed by your company and in use by your customers.

- Your company's process for demonstration, acceptance testing, and certification and validation of interoperability for the standards listed above. If you propose to provide independent validation and verification of capability, the full price of that effort should be described.

- A description of your company's processes for maintenance and upgrades to accommodate new interface technology, new interface standards, updated interface standards, or new Product functionality.

- All supported proprietary, customized, standards-based, and interoperable interfaces, electronic data interfaces, and data transfer functions supported by the Product.

- A description of the Product's current and proposed functions that are available or fully functional only when the system is interfacing with your company's Products or your company's partner's products.

- A list of the Product's current and proposed interfaces that are only fully supported when interoperating with your company's Products or your company's partner's products.

For all of the above items, please describe all the resources required from the Customer and third parties. Include costs and dependencies if known.

RFP Example C: Description of Technology Supporting Interoperability
Note: Requests a complete description of the Product technology. This should be used only if the Customer intends to evaluate the Product's technology and implementation.

Please describe in your response to the proposal your company's implementation of technology relevant to interoperability, including:

- Description of the current and proposed system architecture, including interfaces.

- Description of the current and proposed software architecture, including interfaces.

- Description of the current and proposed hardware architecture, including interfaces.

- Description of the current and proposed application architecture, including interfaces.

RFP Example D: Description of Vendor's Past Support for Interoperability
Note: Requests a complete description of the vendor's corporate activities related to interoperability but not directly related to the Product itself. This should be used only if the Customer intends to evaluate vendors' past commitment and contributions to interoperability.

Please describe in your response to the proposal the efforts and contributions your company has made to achieving medical device interoperability for your products in particular or the industry in general. The response may take any form, but as an example it could include:

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- Your company's participation in interoperability standards consortiums, societies, or other similar organizations developing or promoting interoperability.

- Any relevant public demonstrations, plug-fests, or product implementations that show the interoperability of your company's products.

MD FIRE: CONTRACT TERMS EXAMPLES

Option 1: Complete Interoperability
Note: The purpose of this section is to provide an example of terms for complete interoperability. Language in square brackets [this or that] should be selected as appropriate by the Healthcare Delivery Organization (referred to herein as "Customer" or "HDO").

1. Supplier shall list all external interfaces for each Product, including interface and communication standards and terminology definitions (referred to collectively herein as "interfaces"). This includes listing any interface standards for a Product which Supplier does not intend to implement or conform to. For each of these interfaces, Supplier shall describe:
    a. The unique identifier or name for the interface
    b. The applicable standard or the Supplier's own name for the interface. Examples include but are not limited to ANSI, ASTM, NEMA, ISO DICOM, IEEE, IHE, USB, WiFi, ZigBee, Bluetooth, HL7, and Continua
    c. The standard name and version if applicable, e.g. HL7 2.3
    d. The domain, subset, and profile of the interface as applicable, e.g. IHE Radiology Profile
    e. Whether its classification is "proprietary & closed", "proprietary & open", "standard" (i.e. HL7 or DICOM), "standard with a third party implementation guideline or profile" (e.g. IHE Radiology) or "standard with a third party implementation guideline and third party certification" (e.g. Continua or USB or WiFi)
    f. Whether it is currently in operational use at customer sites, developed but not in use, in development, or planned for development
    g. Product implementation and support plans for the interface – include implementation or discontinuation plans, as applicable
    h. References to the interface's specification – these could be external links to Standards Development Organizations, or the Supplier's own documentation as applicable
    i. A description of the Product functions supported by the interface

    A table illustrating the information required above is shown at the end of the Appendix.

2. During the Term of the Agreement and any subsequent period during which Customer is purchasing support and maintenance services from Supplier for Products, Supplier will implement federally ratified interoperability standards and interoperability specifications for all interfaces described in paragraph 1 above as follows:
    - Applicable specifications published by the Health IT Standards Panel (HITSP)
    - Applicable certification criteria published by the Certification Commission for Health IT (CCHIT)

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- Applicable specifications recognized by the Secretary of US Health and Human Services and required under the federal contracting provisions of US Executive Order 13410
- Other interoperability standards and specifications recognized or required in applicable laws, rules, regulations, and legislation from the federal government and states and districts where HDO operates

Supplier will implement these standards and specifications [before the US Government and its agencies mandate compliance for any final specification] in accordance with HDO project timeline in Exhibit XXX.

3. As part of the Customer's acceptance testing process, Supplier shall demonstrate in the Customer's own test and operational environments that the Products successfully interoperate with Customer's third party equipment and systems in accordance with the requirements in this Exhibit and with the use cases [described in this Agreement, mutually agreed upon by the parties].

4. For any proprietary interfaces, Supplier shall provide to Customer and designated third party suppliers the information necessary for them to understand and test the Product's interface specifications that are in use by Customer and, where needed, a royalty-free license to use these proprietary interfaces with third party products that interoperate with Products in use by Customer.

5. In the event the Product fails to interoperate with third party products and systems in accordance with the Product's integration and interoperability specifications set forth in this Agreement, then Supplier shall remediate the problem at Supplier's cost and shall reimburse Customer for its reasonable costs and expenses resulting from re-work, re-testing, re-certification, and re-validation of the product.

6. For all of these terms, Supplier shall specify whether the capability is available in the proposed Product without a maintenance agreement. If any capability is only available with a maintenance or development agreement, the terms of that agreement shall be fully disclosed and described.

Option 2: Independent lab testing of interfaces

Supplier agrees to have each interface tested and verified by an independent lab approved by Supplier and Customer.[1] All costs from the Supplier and other third parties for independent lab testing and certification shall be listed separately [and paid by Supplier]. Supplier also agrees to obtain any applicable consortia certification for Product interfaces, including without limitation, USB, WiFi, ZigBee, Bluetooth, HL7 and Continua.

Option 3: Connectivity by Clinical Domain
Note: This section provides a means to add requirements by clinical domain. Customer should consider selecting a specific domain if needed.

[1] Such as the Medical Device Plug-and-Play Lab at the Center for Integration of Medicine and Innovative Technology (CIMIT) or the Kaiser Garfield Center

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Product and all subsequent releases and replacement Products shall comply with applicable interoperability standards, guidelines, and certifications in the following domains:

- Acute Care Documentation
- physiological monitors
- ventilators
- patient care beds
- etc.

Option 4: Request for Conformance to Specific Standards
Note: This section provides a means to add conformance to specific standards if not required by other sections.

Product and all subsequent releases and replacement Products shall comply with the following standard:

- (e.g. ASTM xxxx 200x)

Option 5: Commitment to Work towards Interoperability
Purpose: This section is to be used when the Supplier is expected to make a best effort to achieve interoperability, and at the same time to inform the Customer of any issues, barriers, or problems with the current set of standards.

At every release of Product software, either for implementation or maintenance, Supplier shall use best efforts to implement applicable [federally ratified] interoperability standards. Supplier and Customer shall meet quarterly [in-person or by teleconference by mutual agreement] to discuss Supplier's progress towards implementing and conforming to applicable standards. At each meeting, Supplier shall provide the following information:

1. For each interface, a description of the progress and accomplishments made towards conformance with standards
2. For each interface, a list of issues, objections, and problems encountered with the Supplier's Products, third party products, and the Customer's or standards' specifications that prevent or delay conformance

Option 6: Customer Requirements-Gathering Example

Exhibit XXX

This is a placeholder for the Customer to define its program/project timeline with respect to gathering requirements for interoperable interfaces. It is referenced in the Agreement terms. To support this Agreement language, this Exhibit should at a minimum specify:

- When requirements will be delivered from the Customer to the Supplier
- When the Supplier is expected to complete development of interfaces
- When the Supplier is expected to complete testing, validation, and certification of interoperable interfaces

The actual content of this exhibit should be created by the Customer's legal team.

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This table contains examples of the expected level of detail to be provided by Supplier for its external interfaces.

Example Interface Standard Table

Interface Name	Standard	Domain	Type	In use?	Scope of Conformance	Plans	Reference to interface specification	Functions supported
Patient demographics	HL7 2.3	Demographics	Open standard, not validated	In operational use	Partial implementation	No plans to discontinue	www.hl7.org	Receiving and displaying patient demographic data
Patient lab data	Proprietary	Laboratory	Proprietary, open	In operational use	Full	Will be maintained for existing products, but eventually replaced by HITSP standard interface	www.vendorname.com/productsupport/interfacess	Sending patient lab data
Patient lab data	TBD	Laboratory	Open standard, CCHIT validation	Planned for development	Planned to be lab data	Will replace lab data interface within 12 months of ratification of the specification and adoption by the US government	www.hitsp.org	Sending patient lab data to the EMR
Patient weight	IEEE XXX, Continua V1 Guidelines	Disease Management	Open validated standard, Continua guidelines, Continua validation	No	Full & Certified	Planned for delivery in 2009 Q2 products	www.continuaalliance.org	Receiving CHF patient's weight
Contrast injectors	CIA425, Part 2: Injector	CAN-Open Application Profile for Medical Diagnostic, Add-on Modules, Part 2: Injectors	Standard	Yes	Full	No plans to change	http://www.can-cia.org	Connect injectors to CANOpen network for X-ray contrast injections
Pulse Oximeter	IEEE P11073-10404(sm)	Pulse Oximeter	Standard	Yes	Full	No plans to change	https://development.standards.ieee.org/pub/active-pars?n=12	Acquires Pulse Oximeter data
Integrated Clinical Environment (ICE) Data Logger	ASTM F29.21 ICE Part II	ICE system data logging	In process	No	N/A	Will conform within 12 months of publication	www.sdo.org	Continuously log data from patient-centric devices in the ICE
Disease Taxonomy	ICD-11	All	Standard	No	None	Will implement within 18 months of ratification and publication by WHO	http://www.who.int/classifications/icd/ICDRevision/en	All functions supporting clinical documentation

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PostGraduate Assembly in Anesthesiology issue

ANESTHESIOLOGY NEWS

THE INDEPENDENT MONTHLY NEWSPAPER FOR ANESTHESIOLOGISTS

AnesthesiologyNews.com • **December 2008** • Volume 34 Number 12

ASRA Looks To Push Ultrasound in Pain Management

Already firmly entrenched in the operating room, ultrasound is finding its way into virtually every tributary of anesthesiology.

One of the newer areas into which ultrasound has penetrated is pain medicine. In recognition of the increasingly important role of ultrasound in treating chronic pain, a leading anesthesia society has established a special working group to guide the development of this growing subspecialty, from training and education to best practices.

see ***SIG*** page 10

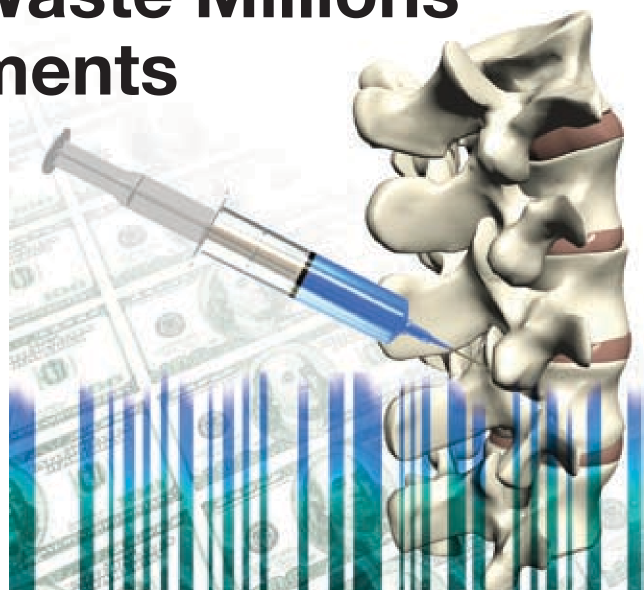
Coding Mistakes for Facet Joint Injections Waste Millions In Medicare Payments

Medicare overpays physicians by $96 million each year for facet joint injections, the result of inappropriate billing codes and insufficient documentation for the services, a new report has found.

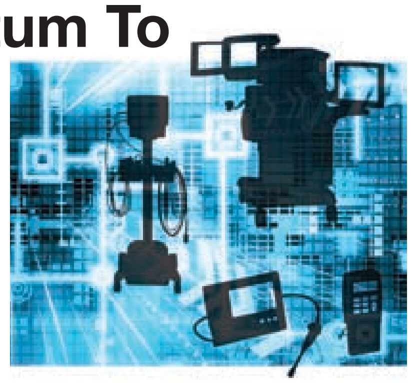
The report says physicians fail to appropriately bill for facet joint injections more than 60% of the time—an error rate pain specialists fear could lead to a government crackdown on the field.

"This report puts [pain specialists] even more so on the radar screen," said Paul Dreyfuss, MD, president of the International Spine Intervention Society (ISIS). "It confirms that there may be inappropriate billing and, potentially, abuse of these procedures."

see ***facet*** page 26



Model Contract Gives Momentum To Interoperability Movement



The movement to create "plug-and-play" interoperability between medical devices is edging toward the long-sought goal of linking the plethora of proprietary equipment, sensors and other electronic technologies to increase patient safety, reduce costs and improve efficiencies in the operating room and other clinical settings.

Among the recent developments, three major health care delivery organizations have drafted and agreed to incorporate interoperability requirements in their contracts with equipment vendors and medical device suppliers. In addition, officials at the FDA, Veterans Administration and other federal agencies are evaluating various plug-and-play standards for possible promulgation. One such set of draft standards is being evaluated for possible dissemination internationally as early as next spring.

"We take plug-and-play functionality for granted when we connect a printer or digital camera to a personal computer. We need that kind of functionality in health care and the operating room where it's almost nonexistent or, if it exists, is proprietary," said Julian M. Goldman, MD, director of MD PnP, an interoperability collaboration based at Massachusetts General Hospital and the Center for Integration of Medicine & Innovative Technology (CIMIT), a

see ***plug*** page 58

INSIDE

NEWPRODUCTS

ECOM™ Endotracheal Cardiac Output Monitor, from **ConMed Corporation,** see page 6.

AS3000 Anesthesia System, from **Datascope Patient Monitoring,** see page 10.

Arrow® StimuCath® Continuous Nerve Block Kits, from **Teleflex Medical,** see page 48.

SPECIALREPORT

The Use of Metaxalone in the Treatment of Low-Back Pain, see insert at page 34.

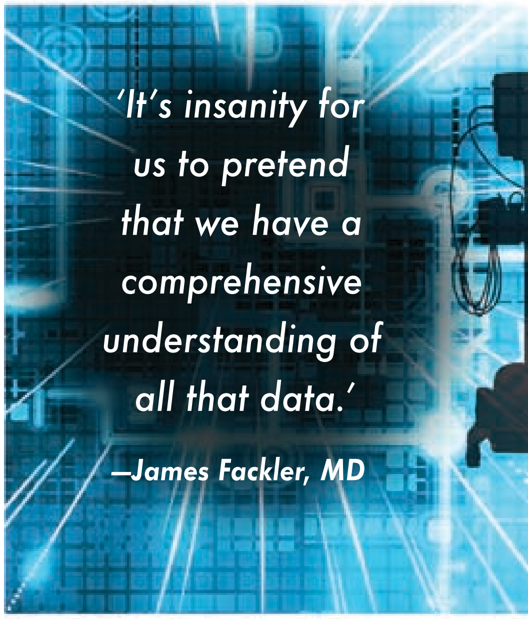
TECHNOLOGY

PLUG CONTINUED FROM PAGE 1

health care technology consortium of Boston-area hospitals and engineering schools.

Although many medical device manufacturers create networked solutions for their own equipment, most products cannot be linked to other equipment used in the OR. The benefits of doing so are tantalizing: The ability to synchronize an x-ray with the breathing of an anesthetized patient in surgery can produce better-quality images; an interoperable plug-and-play network could automatically shut down a laser used in airway surgery if sensors detected oxygen sufficient to pose a combustion threat (*Anesthesiology News,* January 2007, page 1).

Device integration and interoperability could also help physicians make sense of disparate patient data. Sensors and devices from a patient in the intensive care unit can generate up to 350 data elements, said James Fackler, MD, associate professor of anesthesiology and critical care medicine at Johns Hopkins University School of Medicine in Baltimore, and an MD PnP participant. "We ignore most of these data elements because cognitive psychology has demonstrated that humans can only handle up to seven things at once. Frankly, it's insanity for us to pretend that we have a comprehensive understanding of all that data," Dr. Fackler said.



At the 2008 American Society of Anesthesiologists (ASA) annual meeting in October, Dr. Goldman and his colleagues unveiled a white paper including model contracting language for use by hospitals, clinics, insurance companies and other health care organizations. The document, called MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise), urges manufacturers and vendors create or adopt open interoperability standards and interfaces when they become available.

MD FIRE was crafted earlier this year by experts from Massachusetts General Hospital/Partners HealthCare, Johns Hopkins and Kaiser Permanente. The three organizations have agreed to incorporate these requirements into their own contracts and requests for proposals.

Kaiser, the nation's largest private nonprofit health care system, has been a leading proponent of interoperability, pushing for standards in electronic medical records and other technologies for the past several years.

"Our goal is plug-and-play. We want a seamless interconnection and data flow from biomedical devices to and from clinical information systems," said Zachary A. Zimmerman, MS, MD, chief of anesthesia at Kaiser Vallejo and chair of the chiefs of anesthesia for the Permanente Medical Group of Northern California. Since 2006, Kaiser, with more than 8.7 million members and 14,000 physicians nationwide, has required its vendors to comply with medical device and equipment interoperability standards when they are created.

FIRE and ICE

The counterpoint to MD FIRE is MD ICE—Integrated Clinical Environment—a set of interoperability standards being developed by ASTM

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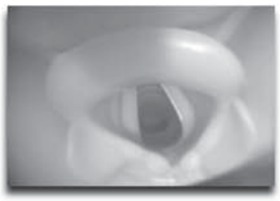

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International, one of the world's largest voluntary standards development organizations. Dr. Goldman, who is past president of the Society for Technology in Anesthesia (STA), chairs the ASTM subcommittee on new specifications for equipment in the integrated clinical environment. Balloting on provisions of MD ICE closed Nov. 15 and the results will be available in the spring, he said.

Although the FDA does not regulate hospitals, it does oversee medical devices, so any interoperability system would likely need to pass regulatory muster or at least have gained the agency's tacit approval. In June 2007, the FDA took part in a two-day workshop on interoperability to "engage with academia, industry and clinicians in deciding how future medical device users might benefit from increased automation and information sharing," agency officials said.

"We have had expressions of interest from several health care organizations to collaborate on the MD FIRE shared interoperable medical device procurement terms, and we also expect similar interest from the federal government," said Dr. Goldman, a member of the editorial advisory board of *Anesthesiology News*.

If medical device interoperability becomes mandatory, it will be a big business. Companies will need to write new software for their equipment to meet plug-and-play standards. In December 2007, an earlier version of Dr. Goldman's standards failed to be approved by the Swiss-based International Organization for Standardization and its affiliated International Electrotechnical Commission.

One person familiar with the situation said major device makers feared that adopting the standards would cut into their profits by forcing them to cooperate with smaller companies.

MD PnP is not the only group pushing for interoperability standards. However, the majority of such efforts have revolved around electronic medical records. For example, 51 vendors and more than 74 clinical information systems participated at the Healthcare Information and Management Systems Society annual conference last March. And of the approximately 80 exhibits displayed at CIMIT's Innovation Congress in October, fewer than five focused on medical device and equipment interoperability, Dyke Hendrickson, a spokesman, said.

Still, progress continues; six clinical societies so far have endorsed medical device interoperability. In October, the ASA and STA adopted a position statement noting that "intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind."

Additional endorsements have come from the Anesthesia Patient Safety Foundation, the Society of American Gastrointestinal and Endoscopic Surgeons, the Massachusetts Medical Society and the World Federation of Societies of Anaesthesiologists.

—*Ted Agres*

Medical devices lag in iPod age

The Boston Globe

Patients' safety is at risk, experts say

By Carolyn Y. Johnson, Globe Staff | December 29, 2008

A 32-year-old woman was on the operating table for routine gall bladder surgery, and doctors needed a quick X-ray. To keep her chest still while the image was shot, her ventilator was switched off. But the anesthesiologist, distracted by another problem, forgot to turn the breathing machine back on. The woman died.

The case is an extreme example of the kind of error that could be prevented if medical devices were designed to talk to each other, says Dr. Julian Goldman, a Massachusetts General Hospital anesthesiologist who has compiled such instances from across the United States to highlight the need for medical device "connectivity." In this case, he says, synchronizing the X-ray machine with the ventilator, so the image was automatically timed to a natural pause in breathing, would have made it unnecessary to turn it off.

As technology moves forward, people expect the electronic devices of everyday life to work together, from cellphones that can call or text-message other phones, to computers that interconnect with a slew of gadgets. But in the medical world, where the stakes are higher, such flexible interconnection is rare. Each device operates in its own silo.

"It is really unacceptable, and it's one of the reasons we're unable to make dramatic improvements in patient safety," said Goldman, a leader in calling for a new generation of medical devices that talk to each other.

Now the push for greater connectedness in hospital electronics is gaining momentum. The goal is devices that can not only plug into one another, but can also "understand" each other and automatically identify potential life-threatening problems sooner than they would have been caught by busy nurses and doctors.

In October, a task force - including Partners HealthCare, Mass. General, Johns Hopkins Medicine, Kaiser Permanente, and the Boston-based Center for Integration of Medicine and Innovative Technology - released sample language that hospitals can incorporate into contracts with vendors of medical devices, requiring that manufacturers create products capable of communicating with other devices using agreed-upon standards.

"My bank can notify me via text message if my account has a low balance, but medical devices can't let me know if my patient is having a critical event," says Dr. Jesse Ehrenfeld, a Mass. General anesthesiologist.

The administration of pain medication is one area where the ability to connect could save lives, advocates say.

A case reported in the Canadian Journal of Anesthesia, for example, describes a 19-year-old patient who accidentally received too much pain medication through an IV pump and died. Such pumps have safety features intended to guard against overdoses, but in most cases they are not hooked up to the monitors tracking the patient's vital signs. That means a dosage error or unexpected reaction that causes the patient to decline could escape notice.

A study published this month in the Joint Commission Journal of Quality and Patient Safety looked at the safety of patient-administered pain medication and found that it is four times more likely to result in patient harm than other medication errors.

At a recent conference, Goldman's Medical Device Plug and Play Interoperability Program demonstrated how problems with such medication systems could be addressed. It presented a series of circuits that could patch together monitors and, when needed, automatically shut off the pump administering pain medication, and call the nurses station.

Dr. Marc J. Bloom, director of perioperative technology at New York University's Langone Medical Center, calls the clutter of wires and cords in operating rooms "malignant spaghetti."

"We work with a lot of high technology in a very tight space," he said. "For us to connect all the devices, you have to run a wire. So if you have 10 devices, you'd have to run not just 10 wires but 100, to interconnect everything in the room. Add to that the fact that if you do connect them all together, they don't speak the same electronic languages."

Ehrenfeld pointed out another danger: increased costs. He's seen a patient come in with an MRI scan saved on a CD, but in a proprietary file format that can't be easily viewed, meaning that another MRI is ordered at considerable cost.

So why hasn't greater connectivity in medical devices been developed before now? There are a variety of reasons.

"At a certain point of development, it's understandable because the vision of the value of connectivity is not really there as the technology is still being developed," said Goldman. On top of that, there has been little demand because "doctors and nurses don't realize things can be better than they are today."

And medical device companies have been slow to change so far, according to Tim Gee, a principal at Medical Connectivity Consulting. Adding interconnectivity could increase companies' liability and costs, and open them up to new competition from other companies, he said.

But companies participate in annual Connectathons, and greater connectivity has become a priority, according to Jeffrey Secunda, associate vice president of technology and regulatory affairs for AdvaMed, a medical device trade association.

"Clearly, the patient benefit is there, and therefore there will be a competitive benefit for companies to pursue this," Secunda said.

Sandy Weininger, senior biomedical engineer at the US Food and Drug Administration, which regulates medical devices, said the agency has been working on the issue of interoperability for about four years, with safety a priority because medical devices are held to a higher standard than consumer electronics.

"Typically, no one is going to die from their phone not working. But they will die if their ventilator or heart-lung machine hiccups or freezes because of interoperability," Weininger said.

Gee, the consultant, predicts that interoperability is likely to emerge from companies that find ways to connect devices, instead of requiring hospitals to replace thousands of functioning units with new, integrated systems.

The turning point may be the arrival of the first truly revolutionary application, such as a medical version of an iPod, that changes people's expectations of their devices. That is what it will take to make "everyone clamor," Weininger said. "As soon as you get the iPod . . . it just mushrooms."

Carolyn Y. Johnson can be reached at cjohnson@globe.com. ■

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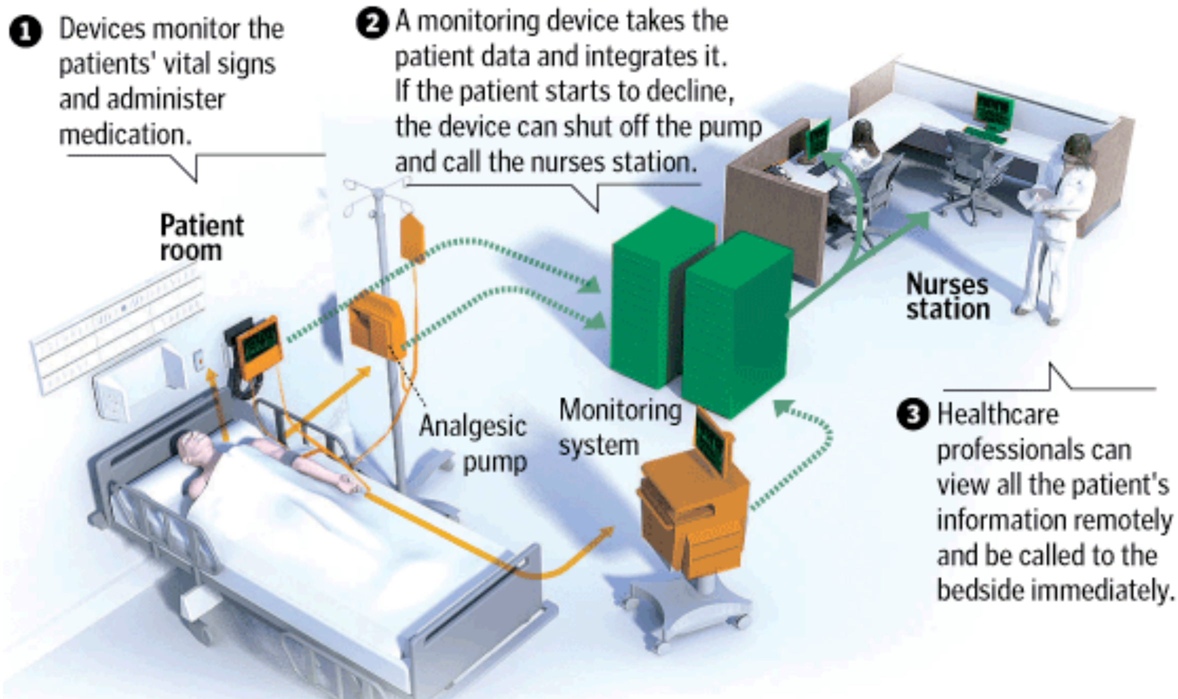
CONNECTED CARE

Doctors from Massachusetts General Hospital and elsewhere say better connectivity in medical devices could increase patient safety.



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By Susan F. Whitehead and Julian M. Goldman, MD

MD FIRE

Hospitals Issue Call for Action on Medical Device Interoperability

We highlighted the importance of medical device interoperability for patient safety in an article in *PSQH* in January/February 2007. Interoperability enables the integration of individual medical devices into a networked system for the care of a high-acuity patient, and will support an infrastructure for innovation in patient safety, treatment efficacy, and workflow efficiency. Such a system can reduce medical errors and healthcare costs to the benefit of patients throughout the continuum of care. In the past year, the primary potential users of such integrated systems—clinicians and healthcare delivery organizations (HDOs)—have begun to strengthen their demand for this vital capability.

Six clinical societies have now endorsed medical device interoperability as enabling improvements to patient safety and healthcare efficiency. These include the Anesthesia Patient Safety Foundation, American Society of Anesthesiologists (ASA), Society of American Gastrointestinal Endoscopic Surgeons, World Federation of Societies of Anaesthesiologists, Society for Technology in Anesthesia, and Massachusetts Medical Society. Similar endorsement language is under consideration by additional groups.

Three leading HDOs—Massachusetts General Hospital/Partners HealthCare System, Johns Hopkins Hospital, and Kaiser Permanente—collaboratively developed draft interoperability requirements that they have agreed to incorporate in their procurement contracts with medical device vendors. The collaborative team—including clinicians, procurement/materials managers, clinical and information systems engineers, and legal counsel from each of the institutions—was convened and led by the Medical Device Plug-and-Play (MD PnP) Interoperability Program and worked together over a 6-month period to develop a white paper and sample sharable contracting language. The resulting document—MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise)—was announced and released at the annual meeting of the ASA in October 2008, and is available for download on the MD PnP web site (http://mdpnp.org). The document's release was followed by a press release from the ASA and a cover article in the December 2008 issue of *Anesthesiology News*.

> The original collaborating institutions are encouraging other hospitals and HDOs to adopt MD FIRE or similar language for contracts and RFPs.

The original collaborating institutions have issued a call to action for interoperability of medical devices and systems—they are encouraging other hospitals and HDOs to adopt MD FIRE or similar language for contracts and RFPs, in order to drive procurement changes that make it clear to medical device vendors what we need. This work is closely aligned with the U.S. FDA's position on interoperability. The document urges device manufacturers to adopt open electronic data interfaces once they are available, and to participate in the development of such interfaces. Additional large national HDOs are currently considering the MD FIRE language.

A set of interoperability standards called ICE—the Integrated Clinical Environment—is currently under development in ASTM International, one of the world's largest standards development organizations. The multipart ICE standard defines the necessary characteristics of a patient-centric clinical environment that can safely support integrated networked medical devices, such as "flight data recorder" capture of network and user data (e.g.

Excerpts from MD FIRE (http://mdpnp.org/MD_FIRE.php)

We HDOs wish to adopt interoperability standards for medical device interconnectivity. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. …Our goal is to document the clinical demand and to strongly encourage the development and adoption of medical device interoperability standards and related technologies.

…We believe that changing the way in which we procure medical devices to integrate requirements for interoperability will provide a way for us to ensure patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information.

keystrokes), and authentication of devices coming onto and going off the network. Part I of ICE is out for ballot, and work is beginning on the drafting of subsequent parts (Device Models and Network Control).

MD FIRE reflects the recognition by HDOs of the need for medical device interoperability in the modern healthcare environment and their deep-felt desire to adopt interoperability standards when available. By releasing the MD FIRE document and encouraging ongoing discussion and improvement of interoperability requirements, HDOs seek to hasten the day when patients and providers can benefit from the same level of interoperability that we all enjoy as consumers of modern computers and consumer electronics that have these capabilities now. PSQH

Susan Whitehead *is the program manager of the Medical Device Plug-and-Play (MD PnP) Interoperability program at CIMIT (Center for Integration of Medicine and Innovative Technology), a consortium based at Partners HealthCare in Boston. She coordinates collaborations, communications, and projects for the multi-disciplinary, multi-institutional MD PnP program, which includes a growing network of more than 600 individuals and 85 institutions. Whitehead may be contacted at swhitehead@partners.org.*

Julian Goldman *is director of the program on interoperability at CIMIT (Center for Integration of Medicine and Innovative Technology), a practicing anesthesiologist in the Massachusetts General Hospital (MGH) "OR of the Future," and a physician advisor to Partners HealthCare Biomedical Engineering at MGH. He is the director of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program, which he founded in 2004 to lead the adoption of open standards and technology for networking medical devices to support high-acuity clinical solutions for improving patient safety and healthcare efficiency. Goldman may be contacted at www.jgoldman.info.*

References

Whitehead, S. F., & Goldman, J. M. (2008). Getting connected for patient safety: How medical device "plug-and-play" interoperability can make a difference. *Patient Safety & Quality Healthcare,* 5(1), 20–26.

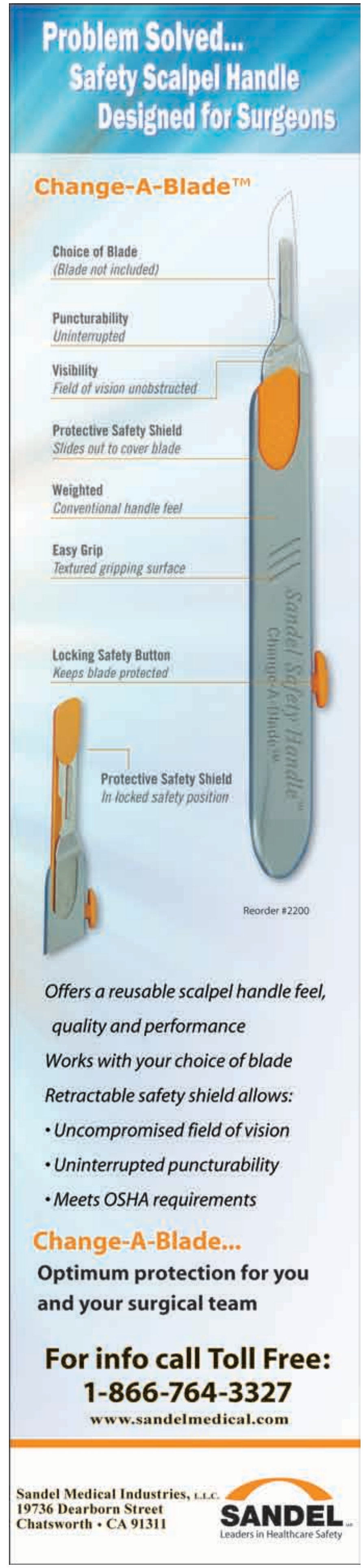
Model contract gives momentum to interoperability movement. (2008). *Anesthesiology News*, 34, (12), 58-59.

"FDA Perspective," 2007 Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS-MD PnP 2007), xii-xiii, (http://tinyurl.com/mdpnpfda)

Option 1: Complete Interoperability

1. Supplier shall list all external interfaces for each Product, including interface and communication standards and terminology definitions (referred to collectively herein as "interfaces"). This includes listing any interface standards for a Product which Supplier does not intend to implement or conform to....

2. During the Term of the Agreement and any subsequent period during which Customer is purchasing support and maintenance services from Supplier for Products, Supplier will implement federally ratified interoperability standards and interoperability specifications for all interfaces described in paragraph 1 above as follows:...



Nxx

Final draft ASTM TC F29.21

ASTM final F-2761

Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model

Élément introductif — Élément central — Partie 1: Titre de la partie

Download from:

<http://mdpnp.org/uploads/F2761-ICE_Part_I_Feb_11_intermediate_draft_changes_accepted.pdf>

DRAFT Not for Distribution

HCMDSS / MD PnP'09

2nd Joint Workshop on High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability

April 16, 2009
San Francisco, CA
Parc 55 Union Square Hotel

Held in Conjunction with CPSWeek 2009

8:15 – 8:30am	Welcome from Workshop Co-Chairs *Insup Lee, PhD, University of Pennsylvania* *Julian M. Goldman, MD, Massachusetts General Hospital / CIMIT*
8:30 – 9:30am	Invited Keynote Address: *David Whitlinger* *President & Board Chair, Continua Health Alliance* *Director, Healthcare Device Standards, Intel Corporation*
9:30 – 10:00am	Break
10:00 – 11:30am	**HCMDSS**
10:00 – 10:10am	CPS Projects in the HCMDSS Domain *Insup Lee*
10:10 – 10:35am	Engineering High Confidence Medical Device Software *A. Ray, R. Jetley, P. Jones*
10:35 – 11:00am	A Tool for Designing High-Confidence Implantable BioSensor Networks for Medical Monitoring *S. Gupta*
11:00 – 11:15am	An Event Driven Framework for Assistive CPS Environments *F. Makedon, Z. Le, H. Huang, E. Becker*
11:15 – 11:30am	Safety Enhancements of Home Lift, Position, & Rehabilitation (HLPR) Chair *J. Zalewski, D. Guo, C. Csavina, J. Sweeney, R. Bostelman, K. Kirsner*
11:30am – 12:30pm	Lunch

12:30 – 2:15pm	**MD PnP**
12:30 – 12:45pm	MD PnP Update *Julian M Goldman*
12:45 – 1:10pm	A Concept for a Medical Device Plug-and-Play Architecture based on Web Services *S. Pöhlsen, S. Schlichting, M. Strähle, F. Franz, C. Werner*
1:10 – 1:35pm	A Publish-Subscribe Architecture and Component-based Programming Model for Medical Device Coordination and Integration *A. King, S. Procter, D. Andresen, J. Hatcliff, S. Warren, W. Spees, R. Jetley, P. Jones, S. Weininger*
1:35 – 2:00pm	A Modular Framework for Clinical Decision Support Systems: Medical Device Plug-and-Play is Critical *M. Williams, F. Wu, P. Kazanzides, K. Brady, J. Fackler*
2:00 – 2:15pm	Standards for Physiological Data Transmission and Archiving for the Support of the Service of Critical Care *J.M. Eklund and C. McGregor*
2:15 – 2:30pm	Break
2:30 – 4:00pm	**Panel: R&D Collaboration Opportunities in HCMDSS and MD PnP** *Moderator: Insup Lee* Panelists: *Helen Gill*, NSF, *Paul Jones*, FDA, *Lui Sha*, University of Illinois
4:00 – 4:30pm	Break
4:30 – 5:15pm	**Medical Networks**
4:30 – 4:45pm	Monitoring and Diagnosis of Networked Medical Hardware and Software for the Integrated Operating Room *S. Bohn, M. Lessnau, O. Burgert*
4:45 – 5:00pm	Wireless Health and the Smart Phone Conundrum *J. Woodbridge, A. Nahapetian, H. Noshadi, M. Sarrafzadeh, W. Kaiser*
5:00 – 5:15pm	Flexible RFID Location System Based on Artificial Neural Networks for Medical Care Facilities *H-J. Wu, Y-H. Chang, I-Ch. Lin, M-Sh. Hwang*
5:15 – 5:20pm	Workshop Wrap-up & Adjourn
5:20 – 6:00pm	Break / Mini-Reception
6:00 – 8:00pm	Clinical Requirements Session *Moderator: Julian M. Goldman, MD*

Preliminary Meeting Report

Medical Device Plug-and-Play Interoperability Program
ICE-PIC: ICE Platform Integration Coordination

making the whole greater than the sum of its parts

Meeting of MD PnP Collaborators

July 30-31, 2009
CIMIT Landsdowne, Cambridge, MA

Introduction

During the two years since our last major plenary meeting, the Medical Device "Plug-and-Play" (MD PnP) Interoperability program has formed collaborations with academic groups funded by NSF and with companies awarded DoD SBIRs/STTRs to work on projects related to medical device interoperability and to the ICE (Integrated Clinical Environment) standard in particular. Collaborative relationships with federal agencies have grown, and include TATRC (U.S. Army Telemedicine & Advanced Technology Research Center), the U.S. FDA (Food & Drug Administration), NSF (National Science Foundation), NIST (National Institute of Standards & Technology), and the Veterans Administration. There has been extensive work on developing the ICE standard, and a gap analysis of ICE use case scenarios vs. available connectivity standards (e.g. IEEE 11073) is being performed by several collaborators. In order to facilitate synergistic progress and accelerate our mutual objectives, the MD PnP program organized a two-day workshop of these collaborators (called the ICE-PIC – ICE Platform Integration Collaboration).

Objectives and Participants

The MD PnP Interoperability program convened a two-day workshop of our collaborators actively working on interoperability- and ICE-related projects. The invitation-only ICE-PIC workshop – supported and hosted by CIMIT – was held on July 30-31 2009 in Cambridge, MA. The purpose of the workshop was to provide a forum to 1) share information about existing projects and where they are headed, 2) discuss what the participants need to further their own work and what they can contribute to the rest of the ICE-PIC community, 3) define the vision and role of the MD PnP Lab, and 4) explore ways to work together going forward to realize our shared vision.

The 40 participants (listed in Appendix A) represented four universities, three healthcare delivery systems, nine companies, and three federal agencies. They included clinical users, biomedical engineers, information systems engineers, federal regulators and program managers, medical device manufacturers, and standards experts. This workshop brought together these individuals as a group for the first time, and resulted in enhanced mutual understanding of our shared objectives for achieving medical device interoperability. Eight of the participants have been part of the MD PnP program since our inaugural meeting in May 2004, and 15 have only become involved in the past year.

Workshop Program

Most of the first day's agenda (see Appendix B) consisted of presentations: an update from Dr. Julian Goldman on MD PnP program highlights from the past two years, project reports from the three universities and five SBIR/STTR companies present, and a summary by Tracy Rausch (DocBox Inc.) of the work to date of the ICE-PAC group, which has been performing a gap analysis of ICE use case scenarios vs. the IEEE 11073 standard. There was extensive Q&A during the talks, followed by a group discussion. Each of the academic groups and companies had been asked to address the following four topics:

- What have you been doing? (current projects)
- Where is your work headed? (vision/goals)
- What do you need to be successful? (requests to the other participants)
- What can you provide to support the community effort?

The needs and potential contributions were captured on flipcharts during the presentations, and were discussed and organized on the second day to produce an initial roadmap for moving forward.

At the end of the first day, participants had a tour of the Center for Medical Simulation and saw demonstrations of use case implementations in the MD PnP Lab. This seeded the discussion the second morning on requirements and the role for the MD PnP Lab in order to make it a more useful resource for our collaborators.

On the second day the group discussed needs that could be filled by the concept of a vendor-neutral laboratory environment such as the MD PnP Lab (see Appendix D). The role that emerged was that of a Medical Device Interoperability Resource Center, which would include virtually-accessible walk-throughs of interoperability demos and a virtual library of data repositories for use cases, device data, simulation tools, and virtual/simulated devices, as well as a well-organized and equipped physical lab for implementing an ICE platform and use cases, for testing ICE-compliance of standards and technologies for device interoperability, and for access to real devices (both wired and wireless) and their documentation. The ICE-PIC group proposed that we identify the five most relevant devices needed for immediate work, and share all the information available on those devices for all to work with. Medical device manufacturers, regulators, IT vendors, and clinicians need to be able to "play" in such a "sandbox", along with academic and clinical engineers. There needs to be a staff of engineers and a revenue stream for sustainability.

Next Steps

The final session involved the group in mapping the needs and contributions identified the first day, in order to generate a plan for mutually beneficial collaborative work going forward. Action items include:

- MD PnP program and Intelligent Automation to figure out how to marshal resources to expand more clinical use case scenarios into "ICE-grade" requirements.
- MD PnP / CIMIT to provide online forum for sharing ideas and work products.
- Formation of a working group to draft initial requirements for the upcoming September meeting to work on ICE parts II and III (ICE controller requirements and device models). This group is led by Tracy Rausch (DocBox Inc.), who also leads ICE-PAC, and includes Dick Moberg (Moberg Research), Jin Lee (Linea Research), Dave Arney (University of Pennsylvania), and John Hatcliff (Kansas State University). Several will participate in the development of ICE parts II and III.
- Formation of a working group to drive requirements for ICE and drive the testing of ICE implementations. They will look at creating a sharable simulated device library to be

- GCAS, TATRC and VA to look into accessibility for the ICE-PIC community to databases of de-identified patient data for research purposes.
- LiveData will make available to the group some of its work on standard vocabulary for medical device decision support rules, to help with clinical scripting.
- Several universities and companies plan to share mock devices, device adapters, simulation tools, middleware engines, and so on.
- MD PnP program to plan another broader plenary meeting next year, with a second ICE-PIC workshop immediately preceding it.

In the workshop wrap-up, Dr. Goldman challenged the group to define where we will go from here in the major areas identified through the discussions:

Virtual Sharing of Documents and Other Resources

- Sean Kennedy will look into CIMIT resources that may facilitate this.
- Julian will set up an area on the existing MD PnP project-sharing website for the ICE-PIC group.

ICE Standard Parts II and III

- Tracy and ICE-PAC will have completed their gap analysis on all the ICE use cases by the time of the Sept ICE meeting.
- Linea will lead the collection of requirements for the ICE controller; they will have their simulator ready to share by that time, as well as their supervisor's requirements from the ICE controller and devices.
- The working group will put together draft requirements for both in advance of the Sept ICE meeting.
- Sandy pointed out that Sebastian Fischmeister has defined some requirements for the controller in his recent workflow.

ICE Platform

- Kansas State has some funding to re-implement the PCA demo in their framework, and could send someone to visit the MD PnP Lab for collaboration.
- Kansas State will write a document within two months that describes how their approach maps to ICE.
- Intelligent Automation has considerable expertise in modeling and simulating networked systems, which could be helpful to this group. David Mayhew will look into how it could be made available.

Regulatory Pathway

- Carl Wallroth pointed out that there is a Global Harmonization Task Force new work item proposal on continual improvement, which should address the exchange/upgrade of software in the field, and he suggested that FDA needs to be involved in that NWIP.
- Carl also recommended that University of Illinois at Urbana-Champaign (UIUC) work through their "sender" concept in the context of ICE.
- Julian recommended that UIUC consider developing guidelines for safe upgrades of software.

Medical Device Plug-and-Play Interoperability Program
ICE-PIC: ICE Platform Integration Coordination
making the whole greater than the sum of its parts

Meeting of MD PnP Collaborators

July 30-31, 2009
CIMIT Landsdowne, Cambridge, MA

AGENDA

THURSDAY, July 30, 2009

10:00 – 10:15am	**Welcome & Introductions** *Julian Goldman*
10:15 – 10:40am	**MD PnP Highlights from past 2 years** *Julian Goldman*
10:40 – 10:50am	**FDA Perspective** *Sandy Weininger*
10:50am – 2:40pm	**Collaborator Presentations** – Q&A following each
	NSF-supported projects
10:50 – 11:10am	**University of Pennsylvania** *Insup Lee*
11:10 – 11:30am	**University of Illinois at Urbana-Champaign** *Cheolgi Kim*
11:30 – 11:50am	**Kansas State University** *John Hatcliff*
	DoD SBIR/STTR projects
11:50 – 12:10pm	**LiveData Inc.** *John Hotchkiss*
12:10 – 12:30pm	**Moberg Research Inc.** *Dick Moberg*
12:30 – 1:15pm	*Lunch Discussion*

NOTE: Dial-in information available on request (swhitehead@partners.org , 617-768-8760)

	DoD SBIR/STTR projects (continued)
1:15 – 1:35pm	**Linea Research Inc.** *Jin Lee*
1:35 – 1:55pm	**GCAS Inc.** *Maurizio Borsotto*
1:55 – 2:15pm	**Intelligent Automation Inc.** *David Mayhew*
2:15 – 2:40pm	**ICE-PAC – Gap Analysis of ICE Use Cases vs IEEE 11073** *Tracy Rausch* ***– DocBox Inc.***
2:40 – 3:00pm	*Break – review and add to flipcharts*
3:00 – 5:00pm	**Discussion of Project Synergies** *Moderator: Julian Goldman*
5:00 – 5:15pm	**Use Case Implementations in the MD PnP Lab** *X-Ray / Ventilator & PCA Safety Demos – Dave Arney*
5:15 – 5:55pm	**Visit MD PnP Lab and View Demos**
6:30 – 8:30pm	*Dinner Discussion*

FRIDAY, July 31, 2009

8:00 –	*Breakfast & coffee available*
8:30 – 8:45am	**Recap of where we ended up yesterday** *Julian Goldman*
8:45 – 9:45am	**Discussion of MD PnP Lab as Collaborative Resource** *Moderators: Rick Schrenker, Sandy Weininger*
9:45 – 10:30am	**What is the best possible outcome?** **Review of Needs (Summary Charts)** *Julian Goldman*
10:30 – 10:45am	*Break*
10:45am – 12:45pm	**Strategic planning discussion:** **Realizing the vision** **Identifying synergies and planning collaboration** • **Projects** • **Funding** *Moderator: Julian Goldman*
12:45 – 1:00pm	**Wrap-up, Next Steps** *Julian Goldman*
1:00pm	***Adjourn***

NOTE: Dial-in information available on request (swhitehead@partners.org , 617-768-8760)

Medical Device Plug-and-Play Interoperability Program
ICE-PIC: ICE Platform Integration Coordination

July 30-31, 2009 Meeting Participants

DoD SBIRs

John Hotchkiss, LiveData Inc.
Jin Lee, Linea Research Corporation
Lino Velo, Linea Research Corporation
Dick Moberg, Moberg Research Inc.
Ilya Livshits, Moberg Research Inc.
Maurizio Borsotto, GCAS Inc.
David Mayhew, Intelligent Automation Inc.

NSF Cyber Physical Systems Projects

Insup Lee, University of Pennsylvania
Oleg Sokolsky, University of Pennsylvania
Dave Arney, University of Pennsylvania
Cheolgi Kim, University of Illinois at Urbana-Champaign
Mu Sun, University of Illinois at Urbana-Champaign
John Hatcliff, Kansas State University
Sam Procter, Kansas State University

Federal Government

Tim Cromwell, Veterans Administration
Ron Marchessault, TATRC / DoD
Sandy Weininger, FDA / CDRH

ICE-PAC / Industry

Tracy Rausch, DocBox Inc.
Ken Fuchs, Draeger Medical
Carl Wallroth, Draeger Medical
John Rhoads, Philips Medical

Partners / MGH / CIMIT

Julian Goldman, CIMIT / MGH
Penny Ford-Carleton, CIMIT
Sean Kennedy, CIMIT
Sue Whitehead, CIMIT
Rick Schrenker, MGH Biomedical Engineering
Luis Melendez, MGH Biomedical Engineering
Leo Hannenberg, MGH Biomedical Engineering
Chris Smith, MGH Biomedical Engineering
Rick Hampton, Partners HealthCare Information Systems
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By Phone

Steven Dain, University of Western Ontario
Sebastian Fischmeister, University of Waterloo
Frank Goodman, Integrated Medical Systems (GCAS partner)
Matthew Hanson, Integrated Medical Systems (LSTAT)
Paul Jones, FDA / CDRH
Kamran Sayrafian-Pour, NIST

CIMIT® Center for Integration of Medicine & Innovative Technology — PARTNERS HealthCare — MD PnP™ Getting connected for patient safety™

Advancing the Adoption of Medical Device "Plug-and-Play" Interoperability to Improve Patient Safety and Healthcare Efficiency

- a white paper from the MD PnP Program -

Unlike the connected "plug-and-play" environment of networked computers and modern consumer electronics, medical devices – essential for the practice of modern medicine – have traditionally been designed to operate independently using proprietary electronic data interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems are no longer acceptable. Medical devices must easily integrate with other vendors' equipment, software, and systems in order to improve healthcare quality, reduce healthcare costs, and provide for more accurate, comprehensive, and secure management of health information.

The importance of applying modern systems engineering solutions, such as interoperability, to improve patient safety and reduce costs was addressed in a National Academy of Sciences report entitled *Building a Better Delivery System: A New Engineering/Health Care Partnership*[1]. However, medical device vendors have not widely adopted cross-vendor standards-based interoperability for medical device integration. Currently, when cross-vendor medical device integration is required, customized device interfaces must be developed, with high cost, long development time, and incomplete functionality.

Standards-based medical device interoperability can provide real-time comprehensive population of the electronic health record (EHR) and lay a foundation for the more comprehensive improvements in patient safety and quality that can arise from the integration of medical devices. Interoperability will enable the creation of integrated "error-resistant" medical systems to support advanced capabilities such as automated system readiness assessment; physiologic closed loop control of medication delivery, ventilation, and fluid delivery; decision support; safety interlocks; smart alarms; monitoring of device performance; plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; comprehensive data collection (like a "flight recorder") for the analysis of near-misses and adverse events; enhanced disaster preparedness and response capabilities; and other innovations to improve patient safety, treatment efficacy, and workflow efficiency. These improvements in workflow will reduce medical errors and healthcare costs to the benefit of patients throughout the continuum of care – from the home, to out-of-hospital transport, and to clinical areas as diverse as the OR, ICU, and general hospital ward.

Barriers to the widespread adoption of interoperability have included the absence of proven standards for data communication and control, and a lack of reliable and safe system architectures. Moreover, there have been regulatory concerns, liability concerns, and a scarcity of well-defined use cases. These barriers underscore the need for an integrated clinical environment "ecosystem" that would include system functions such as enabling decision support algorithms, data logging, data security, device authorization, and connectivity to the hospital information system. These functions would provide a complete systems solution that meets regulatory, safety, and clinical requirements.

About the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program

The MD PnP program was established in 2004 to lead the evaluation and adoption of open standards and technology for medical device interoperability to support clinical innovation. The program is affiliated with Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare, with additional support from TATRC (U.S. Army Telemedicine & Advanced Technology Research Center). Having evolved from the OR of the Future program at MGH, the MD PnP program remains clinically grounded. We have taken a multi-faceted approach to begin addressing key barriers to achieving interoperability, including the development and support of suitable open standards (e.g. the Integrated Clinical Environment, or ICE), and the elicitation, collection and modeling of clinical use cases to define engineering requirements for interoperability. The MD PnP program received CIMIT's 2007 Edward M. Kennedy Award for Healthcare Innovation.

Since the program's inception, more than 700 clinical and engineering experts, and representatives of more than 85 companies and institutions have participated in plenary workshops/conferences, working groups, and focus groups to contribute to ongoing program activities. Our multidisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, FDA, university computer and information science groups at Pennsylvania, Illinois/Urbana-Champaign, Waterloo, and New Hampshire, Draeger Medical Systems, DocBox Inc., Moberg Research Inc., LiveData Inc., Mitre Corporation, IXXAT, NSF/CPS, Geisinger Health System, as well as the Partners HealthCare System community (including clinical and biomedical engineering departments at Massachusetts General Hospital, and Brigham & Women's Hospital and Partners HealthCare Information Systems).

The CIMIT MD PnP Lab opened in May 2006 to provide a vendor-neutral "sandbox" to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. In the Lab we are developing demonstrations of interoperability-based patient safety improvements, such as improving the safety and quality of portable x-rays, and patient-controlled analgesia systems that are used for pain management.

Leading Healthcare Delivery Organizations (HDOs) wish to adopt emerging interoperability standards for medical device connectivity. As a result of collaboration with the MD PnP program, Kaiser Permanente in 2006 began to include limited requirements for medical device interoperability in vendor contracts. In 2008 MGH/Partners HealthCare and Johns Hopkins Medicine joined the collaboration to issue a nationwide Call to Action to improve patient safety by including medical device interoperability requirements as essential elements in vendor selection criteria and procurement processes. This collaboration has produced sample RFP and contracting language that is being widely shared with other institutions as well as device manufacturers. For additional information, see the white paper titled MD FIRE – "Medical Device Free Interoperability Requirements for the Enterprise" (available at our web site).

Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency". Since the first clinical society endorsement in March 2007, the need for medical device interoperability has been endorsed by seven societies, most recently the American Medical Association and the Massachusetts Medical Society:

> "RESOLVED, That our American Medical Association (AMA) believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation."

Key MD PnP Program projects include:

- Eliciting clinical scenarios to inform interoperability solutions; this includes identifying adverse events and near misses that could have been avoided through the integration of medical devices and IT systems
- Compiling a repository of interoperability use cases that can be shared
- Developing a clinical requirements acquisition and analysis methodology that enables use case scenarios to be specified at the level of detail needed to derive engineering requirements, including both functional and quality requirements
- Developing a new open standard for a patient-centric "Integrated Clinical Environment" (ICE) and informing changes to related existing standards – the ICE standard is being advanced within ASTM International
- Preparing an open ICE research platform to deploy and evaluate reference implementations of proposed standards, technologies, and products
- Defining a safe, "least-burdensome" regulatory pathway for patient-centric networked medical devices, in partnership with the U.S. FDA

How You Can Participate

- ***Clinicians*** can contribute clinical scenarios (or "use cases") to ensure that new interoperability standards and technologies will enable meaningful clinical solutions. Diversity of use cases increases the likelihood of effective and generalizable solutions.
- ***Engineers*** can analyze clinical use cases to generate functional specifications, assess current standards to perform "gap analyses", and evaluate proposed technologies. Diverse engineering expertise is essential.
- ***Healthcare delivery organizations*** can specify performance requirements, and require adherence to medical device interoperability language in vendor contracts, adopting the sample language now available and continuing to refine it. Widespread adoption of interoperability will happen only when there is recognized consumer demand.
- ***Regulatory agencies*** can facilitate regulatory clearance of interoperable medical devices, creating new regulatory paradigms as needed.
- ***Medical device manufacturers*** can participate in the development and adoption of interoperability standards, and partner with the MD PnP Program to develop a shared interoperability testing and use-case demonstration environment.
- ***Interoperability promoting organizations*** can support revision of existing standards to meet clinical requirements, collaborate on clinical use case implementations in the MD PnP Lab, and ensure that through collaboration we shepherd the adoption of medical device interoperability to empower innovation in the safety and efficiency of health care.

Learn more at http://www.mdpnp.org, including links to MD FIRE contract terms and the ASTM ICE standard, or contact us using the information below.

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[1] National Academies Press, 2005, Recommendation 4-3